UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION THIS DOCUMENT RELATES TO: All Actions	**MDL No. 2419** **Master Dkt No. 1:13-md-2419-RWZ** **Honorable Rya W. Zobel** **SECOND AMENDED MASTER COMPLAINT**[1] **DEMAND FOR JURY TRIAL**

[1] At the Status Conference conducted by the MDL Court on February 17, 2015 the PSC advised the Court that it would "amend the master complaint to remove certain counts that this Court has already ruled on." Accordingly, this Second Amended Master Complaint incorporates (i) the allegations contained in the original Master Complaint filed on November 5, 2013 (Doc. 545), and (ii) the First Amendment to Master Complaint filed on January 31, 2014 (Doc. 832), with amendments to reflect the rulings of the Court on several dispositive motions since the original filing. See, e.g., Doc.'s 1360, 1556, 1642 and 1643. Although several defendants have signed settlement agreements, allegations concerning those defendants remain in the Second Amended Master Complaint pending final approval of those settlement agreements through confirmation of the Chapter 11 bankruptcy plan.

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I. INTRODUCTION

1. This multidistrict litigation arose as a result of a widespread outbreak of fungal meningitis and other infections that has affected individuals in at least 20 states and has caused over 64 deaths. To date, over 751 people have been diagnosed with meningitis, fungal infections and/or abscesses, and other injuries.

2. The United States Food and Drug Administration ("FDA") and the Centers for Disease Control and Prevention ("CDC") have confirmed the presence of fungus in unopened vials of NECC's methylprednisolone acetate ("MPA"). The FDA and CDC have also identified bacteria and/or fungus present in NECC-supplied preservative-free injectable betamethasone, preservative-free triamcinolone, and cardioplegia solution. Some of the contaminants identified in these products are known to cause human disease.

3. No one disputes that the contaminated products that caused these horrific injuries were made by New England Compounding Pharmacy, Inc., doing business as the New England Compounding Center ("NECC"). No one seriously disputes that the deplorable conditions at NECC contributed to this outbreak. But the story does not begin or end with NECC: Multiple actors contributed to the chain of events that lead to these 64 deaths.

4. Defendant Liberty Industries, Inc. ("Liberty") designed, manufactured, and installed the cleanrooms used to compound, mix, prepare, and assemble the contaminated products. Liberty's cleanrooms contained defects that made them unsuitable for their intended use and vulnerable to manufacture of contaminated products. Without Liberty, there would have been no clean rooms for NECC to compound medicines in. And without the defects in Liberty's clean rooms, the contamination may well have been avoided.

5. Defendant UniFirst Corporation ("UniFirst") was hired by NECC to clean the NECC and Ameridose clean rooms, including the clean rooms where the contaminated products

were manufactured. UniFirst advertises that its services will "improve the safety and cleanliness" of a business facility. UniFirst contracted with NECC to, and did, provide cleaning services to NECC and/or Ameridose, including with respect to the clean rooms. NECC's internal records report numerous instances of reported mold and bacterial contamination in the months leading up to the outbreak. UniFirst failed to provide adequate cleaning services that would have prevented contamination of the drugs made in those clean rooms.

6. Not one person would have developed a fungal infection if hospitals, clinics, healthcare facilities, and/or physicians had not given these contaminated medications to patients. Around 80 hospitals, clinics, healthcare facilities and/or physicians in at least 20 states injected patients with contaminated drugs from NECC. These clinics ordered these medications (often with fake patient names), purchased the contaminated medications, received the contaminated medications, stored the contaminated medications, and injected the contaminated medications into patients – often dozens of patients. Clinics often disregarded the prevailing industry guidelines and Massachusetts pharmacy regulations requiring individual medications to be compounded in response to receiving a prescription for a particular patient. Clinics did so out of convenience and greed: ordering large doses of injectable steroids in bulk allowed them to stock their shelves without going through the "hassle" (but really safeguard) of identifying particular patients who would receive the drug. And NECC's price for MPA was, generally, lower than the prices for brand name methylprednisolone acetate (depomedrol) manufactured by Pfizer.

7. Plaintiffs seek compensatory and exemplary damages, and all other available remedies as a result of injuries caused by NECC's defective products and/or services. Plaintiffs make the following allegations based upon their personal knowledge and upon information and belief, as well as upon their attorneys' investigative efforts.

8. We focus here on the unaffiliated defendants. This complaint does not include allegations against NECC, Ameridose LLC, Alaunus Pharmaceuticals, Inc., GDC Holdings, Barry Cadden, Lisa Conigliaro Cadden, Doug Conigliaro, Carla Conigliaro, Greg Conigliaro, or Glenn Chin. The PSC has moved to lift discovery against these individuals and corporations, but we leave formal allegations against the affiliated defendants for another day.

9. This master complaint is filed for administrative purposes only. It does not replace or supersede the complaints associated with existing civil actions. Plaintiffs' counsel will have an opportunity to sign on to facts and allegations set forth in this complaint through the Short Form Complaint mechanism. This complaint, standing on its own, only serves to provide a factual basis and sample counts for individual plaintiffs.

II. JURISDICTION AND VENUE

10. This Court has original, diversity jurisdiction over the claims of Plaintiffs pursuant to 28 U.S.C. §1332 (a), as the Plaintiffs and Defendants are citizens of different States and the amount in controversy is greater than $75,000.00.

11. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1334(b) because, as described herein, each claim asserted is related to a case under title 11, because the outcome of the proceeding could have some effect on the bankruptcy estate.

12. On December 21, 2012, NECC filed a petition for Bankruptcy protection under Chapter 11 of the Bankruptcy Code: In re: New England Compounding Pharmacy, Inc., Debtor, United States Bankruptcy Court for the District of Massachusetts Case no. 12:19882 HJB. A United States Trustee was subsequently appointed to administer the Bankruptcy Estate.

13. Adversarial cases seeking recovery of damages for the benefit of the bankruptcy estate and its unsecured creditors have been filed in NECC's bankruptcy against each NECC related entity.

14. Lawsuits alleging death or injury based on contaminated MPA have been filed around the country. On February 12, 2013, the Judicial Panel on Multidistrict Litigation (MDL No. 2419) issued an order under 28 U.S.C. § 1407 transferring various federal-court proceedings to this Court, thereby making this district the proper venue for the filing of this Master Complaint.

15. Venue is proper under 28 U.S.C. § 1391, as a substantial amount of activity giving rise to the claims occurred in this District.

16. In addition or in the alternative to the bases for jurisdiction already asserted, this Court has subject-matter jurisdiction over all claims against Defendants located in states other than Massachusetts pursuant to 28 U.S.C. § 1367 in that all such claims are so related to claims in this action within the original jurisdiction of this Court that they form part of the same case or controversy under Article III of the United States Constitution.

III. PARTIES

Plaintiffs

17. Plaintiffs are individuals who suffered death, injury, or distress as a direct and proximate result of being administered one or more NECC Contaminated Drugs compounded, sold and distributed by the NECC and the Affiliated Defendants (as defined below) and administered by a defendant healthcare provider.

18. This Master Complaint is filed as an administrative tool in accordance with the directions and order of this Court. Accordingly, there are no "party plaintiffs" to this document. However, to the extent an individual by his or her attorney hereafter files a Short Form Complaint or a pleading by way of adoption, then it is alleged that Plaintiff is a resident of the state set forth in that pleading and is an individual who has suffered damages as a result of being administered one or more NECC Contaminated Drug compounded, sold, distributed or

administered by Defendants and/or is the lawful spouse, child or parent of such person who has suffered a loss of consortium or society, or is the lawful representative of the estate of such person or a person entitled to recover damages and compensation pursuant to the laws of the state that will govern their case.

Defendants

19. This Master Complaint has been filed as an administrative tool in accordance with directions and order of this Court, including the Court's Order of November 4, 2013 [Dkt. No. 542]. This Master Complaint does not name as parties Barry J. Cadden, Gregory Conigliaro, Lisa Conigliaro Cadden, Douglas Conigliaro, Carla Conigliaro, Glenn A. Chin, Alaunus Pharmaceutical, LLC; Ameridose, LLC, Medical Sales Management, Inc., GDC Properties Management, LLC , and Medical Sales Management SW, Inc. (hereinafter "Affiliated Defendants"). Nor does it name entities that have agreed to mediation pursuant to this Court's Mediation Order [Dkt. No. 502]. Plaintiffs reserve the right to amend this Master Complaint at the direction of the Court, to add allegations and claims against individuals or entities currently omitted and to add or amend allegations against Defendants named herein based, in part, on further discovery.

20. Defendant Liberty Industries, Inc. is a Connecticut corporation with its principal place of business at 133 Commerce Street, East Berlin, Connecticut 06023. Liberty designs, manufactures, distributes, and installs cleanrooms and contamination control supplies both in the United States and worldwide. Liberty manufactured, constructed, installed, and/or designed all NECC and Ameridose cleanrooms at the Framingham, Massachusetts facility. The cleanrooms manufactured, constructed, installed and/or designed for NECC and/or Ameridose contained

defects that made them unsuitable for their intended use and were a direct and proximate cause of injury to Plaintiffs.

21. Defendant UniFirst Corporation is a corporation duly organized and existing under and by virtue of the laws of the State of Massachusetts, with its principal place of business located at 68 Jonspin Road, Wilmington, MA 01887. It may also do business as UniClean Cleanroom Services, and shall be referred to as "UniFirst." UniClean is a division of UniFirst. UniFirst's corporate mission is to be recognized as the quality leader in the cleaning and garment industry. UniFirst also represents that its services will "improve the safety and cleanliness" of a business facility when hired to perform services there. UniFirst at all material times contracted with NECC to provide cleaning services, including cleaning the "cleanrooms" used to manufacture and/or compound drugs, including NECC Contaminated Drugs.

22. The CDC identified the following facilities which received recalled lots of MPA from NECC:[2]

Facility Name	Phone Number	City	State
California			
CYPRESS SURGERY CENTER Principal place of business located at: 842 S Akers Road Visalia, CA 93277	559-740-4094	VISALIA	CA
ENCINO OUTPATIENT SURGICENTER Principal place of business located at: 16311 Ventura Boulevard #580 Encino, CA 91436	818-986-1037	ENCINO	CA
UKIAH VALLEY MEDICAL CENTER* Principal place of business located at: 275 Hospital Drive Ukiah, CA 95482	707-463-7345	UKIAH	CA

[2] This list omits clinics that have opted to mediate their claims pursuant to the Court's Mediation Order.

UNIVERSAL PAIN MANAGEMENT Principal place of business located at: 819 Auto Center Drive Palmdale, CA 93551	661-267-6876 x166	PALMDALE	CA
Connecticut			
INTERVENTIONAL SPINE AND SPORTS MED 1625 Straits Turnpike, Ste. 205 Middlebury, CT 06762	203-598-7246	MIDDLEBURY	CT
Florida			
FLORIDA PAIN CLINIC Principal place of business located at: 2300 S. Pine Ave, Suite B Ocala, FL 34471	352-237-5906	OCALA	FL
INTERVENTIONAL REHABILITATION CENTER Principal place of business located at: 1549 Airport Blvd., Ste. 420 Pensacola, FL 32504	850-484-8800	PENSACOLA	FL
MARION PAIN MANAGEMENT CENTER Principal place of business located at: 1737 A SE 28th Loop Ocala, FL 34471-1079	352-622-1845	OCALA	FL
NORTH COUNTY SURGICENTER Principal place of business located at: 4000 Burns Road Palm Beach Gardens, FL 33410	561-626-6446	PALM BEACH GARDENS	FL
PAIN CONSULTANTS OF WEST FLORIDA Principal place of business located at: 4624 N. Davis Highway Pensacola, FL 32503	850-494-0000	PENSACOLA	FL
SURGERY CENTER OF OCALA Principal place of business located at: 3241 SW 34th Street Ocala, FL 34474 Registered Agent Address: CT Corporation System 1200 South Pine Island Road Plantation, FL 33324	352-237-5906	OCALA	FL
SURGICAL PARK CENTER Principal place of business located at: 9100 87th Avenue	305-271-9100 x226	MIAMI	FL

Miami, FL 33176 Registered Agent Address: CT Corporation System 1200 South Pine Island Road Plantation, FL 33324			
Georgia			
FORSYTH STREET AMBULATORY SURGURY CENTER Principal place of business located at: 1610 Forsyth Street Macon, GA 31201	478-749-1610	MACON	GA
Idaho			
PAIN SPECIALISTS OF IDAHO Principal place of business located at: 2375 East Sunnyside Road, Ste. J Idaho Falls, ID 83404 Registered Agent Address: 3400 Merlin Drive Idaho Falls, ID 83404	208-522-7246	IDAHO FALLS	ID
WALTER KNOX MEMORIAL HOSPITAL Principal place of business located at: 1202 E. Locust Street Emmett, ID 83617	208-365-3561 x3342	EMMETT	ID
Illinois			
APAC CENTERS FOR PAIN MANAGEMENT Principal place of business located at: 2450 Wolf Road, Suite D Westchester, IL 60154 Entity Address: 425 Joliet Street, Ste. 400 Dyer, IN 46311	708-483-7007	WESTCHESTER	IL
APAC CENTERS FOR PAIN MANAGEMENT Principal place of business located at: 2860 N Broadway Street Chicago, IL 60657 Entity Address: 425 Joliet Street, Ste. 400 Dyer, IN 46311	773-935-2760	CHICAGO	IL
THOREK MEMORIAL HOSPITAL Principal place of business located at: 850 W Irving Park Road, Ste. 306 Chicago, IL 60613	773-975-6734	CHICAGO	IL

Indiana			
AMBULATORY CARE CENTER LLC Principal place of business located at: 1125 Professional Boulevard Evansville, IN 47714	812-475-1800	EVANSVILLE	IN
FORT WAYNE PHYSICAL MEDICINE Principal place of business located at: 5750 Coventry Lane, Ste. 101 Fort Wayne, IN 46804 Registered Agent Address: 1400 One Summit Square Fort Wayne, IN 46802	260-436-9337	FORT WAYNE	IN
OSMC OUTPATIENT SURGERY CENTER Principal place of business located at: 2310 California Road Elkhart, IN 46514	574-266-4173	ELKHART	IN
UNION HOSPITAL Principal place of business located at: 1606 N. 7th Street Terre Haute, IN 47804	812-238-4964	TERRE HAUTE	IN
WELLSPRING Principal place of business located at: 2400 North Park, Ste. 20 Columbus, IN 47203	812-376-0700	COLUMBUS	IN
Maryland			
BALTIMORE PAIN MANAGEMENT Principal place of business: 3215 Bancroft Road Baltimore, MD 21215 Registered Agent Address: Jeffrey Kagan 106 Old Court Road, Ste. 104 Baltimore, MD 21208	410-682-5040	BALTIMORE	MD
BERLIN INTERVENTIONAL PAIN MANAGEMENT Principal place of business located at: 10308 Old Ocean City Boulevard Berlin, MD 21811	410-641-3759	BERLIN	MD
BOX HILL SURGERY CENTER Principal place of business located at: 100 Walter Ward Boulevard Abingdon, MD 21009	410-877-8141	ABINGDON	MD

Registered Agent Address: L. Stephen Hess, Esq. 2100 East Pratt Street, 26th Floor Baltimore, MD 21202			
GREENSPRING SURGERY CENTER Principal place of business located at: 6080 Falls Road, Ste. 203 Baltimore, MD 21209	410-653-0077	BALTIMORE	MD
HARFORD COUNTY ASC, LLC Principal place of business located at: 1952 A. Pulaski Highway Edgewood, MD 21040	410-538-7000	EDGEWOOD	MD
PAIN MEDICINE SPECIALISTS Principal place of business located at: 8322 Bellona Avenue, Ste. 330 Towson, MD 21204	410-825-6945	TOWSON	MD
SURGCENTER OF BEL AIR Principal place of business located at: 209 Thomas Street Baltimore, MD 21014 Registered Agent Address: 421 S Union Avenue Havre De Grace, MD 21078	410-638-5523	BEL AIR	MD
Michigan			
MICHIGAN NEUROSURGICAL INSTITUTE Principal place of business located at: 4620 Genesys Pkwy Grand Blanc Township, MI 48439	810-606-7112	GRAND BLANC	MI
MICHIGAN PAIN SPECIALISTS Principal place of business located at: 2305 Genoa Business Park Drive, Ste. 210 Brighton, MI 48114 Registered Office Address: 135 S Prospect Street Ypsilanti, MI 48198	734-995-7246	BRIGHTON	MI
NEUROMUSCULAR & REHABILITATION Principal place of business located at: 3988 W Royal Drive Traverse City, MI 49684	231-935-0860	TRAVERSE CITY	MI
SOUTHEAST MICHIGAN SURGICAL HOSPITAL	586-427-1000	WARREN	MI

Principal place of business located at: 21230 Dequindre Road Warren, Michigan 48091 Registered Agent Address: 601 Abbot Road East Lansing, Michigan 48823			
Minnesota			
MAPS-EDINA MEDICAL PAIN CLINIC Principal place of business located at: 7400 France Avenue South, Ste. 102 Edina, MN 55435	763-537-6000	MINNEAPOLIS	MN
MAPS-MEDICAL ADVANCED PAIN Principal place of business located at: 480 Osborne Rd., Ste. 260 Fridley, MN 55432	763-537-6000	FRIDLEY	MN
MEDICAL ADVANCED PAIN SPECIALISTS Principal place of business located at: 2104 Northdale Blvd. NW, Ste. 220 Coon Rapids, MN 55433	763-537-6000 x238	SHAKOPEE	MN
MEDICAL ADVANCED PAIN SPECIALISTS Principal place of business located at: 2104 Northdale Blvd. NW, Ste. 220 Coon Rapids, MN 55433	763-537-6000	MAPLE GROVE	MN
MINNESOTA SURGERY CENTER Principal place of business located at: 2104 Northdale Blvd. NW, Ste. 220 Coon Rapids, MN 55433	763-767-7139	EDINA	MN
MINNESOTA SURGERY CENTER- Principal place of business located at: 2104 Northdale Blvd. NW, Ste. 220 Coon Rapids, MN 55433	763-537-6000	MAPLE GROVE	MN
North Carolina			
HIGH POINT SURGERY Principal place of business located at: 600 North Lindsay Street High Point, NC 27262	336-878-6048	HIGH POINT	NC
NORTH CAROLINA ORTHOPAEDIC CLINIC Principal place of business located at: 3609 Southwest Durham Drive Durham, NC 27707	919-403-5148	DURHAM	NC
SURGERY CENTER OF WILSON Principal place of business located at:	252-237-5649	WILSON	NC

1709 Medical Park Drive Wilson, NC 27893 Registered Agent Address: CT Corporation System, 150 Fayetteville St. Box 1011 Raleigh, NC 27601			
New Hampshire			
DR. O'CONNELL'S PAIN CARE CENTER Principal place of business located at: 255 RT. 108 Somersworth, NH 03878 Registered Agent Address: Michael J O'Connell, M.D. 255 State Route 108 S1 Somersworth, NH 03878	603-335-5070	MERRIMACK	NH
DR. O'CONNELL'S PAIN CARE CENTERS, INC Principal place of business located at: 255 RT. 108 Somersworth, NH 03878	603-692-3166	SOMERSWORTH	NH
New Jersey			
CENTRAL JERSEY ORTHOPEDICS SPECIALISTS PC Principal place of business located at: 1907 Park Ave., Ste. 102 South Plainfield, NJ 07080	908-561-2122	SOUTH PLAINFIELD	NJ
EDISON SURGICAL CENTER Principal place of business located at: 10 Parsonage Rd. Edison, NJ 08837	732-452-0123	EDISON	NJ
IF PAIN ASSOCIATES / ISAIAH FLORENCE Principal place of business located at: 222 Cedar Lane, Ste. 210 Teaneck, NJ 07666	201-287-1100	TEANECK	NJ
PREMIER ORTHOPEDICS SURG. ASSOC., LLC Principal place of business located at: 352 S. Deslea Drive Vineland, NJ 08360	856-690-1750	VINELAND	NJ
COMPREHENSIVE PAIN MANAGEMENT Principal place of business located at: 270 S. Sparta Ave.	973-796-5216	SPARTA	NJ

Sparta, NJ 07871			
SOUTH JERSEY HEALTH CARE Principal place of business located at: 501 West Front Street Elmer, NJ 08318	856-363-1558	ELMER	NJ
SOUTH JERSEY HEALTHCARE Principal place of business located at: 1505 West Sherman Ave. Vineland, NJ 08360	856-641-7557	VINELAND	NJ
Nevada			
SAHARA SURGERY CENTER Principal place of business located at: 2401 Paseo Del Prado Las Vegas, NV 89102	702-362-7874	LAS VEGAS	NV
New York			
BUTANI, SUNIL H., PHYSICIAN PC Principal place of business located at: 184 Old Country Rd. Mineola, NY 11501	516-747-5042	MINEOLA	NY
OBOSA MEDICAL SERVICES Principal place of business located at: 11 Golden Rd. Montebello, NY 10901	914-530-2323	MOUNT VERNON	NY
ROCHESTER BRAIN AND SPINE Principal place of business located at: Seth M. Zeidman, M.D. 400 Red Creek Dr., Ste. 120 Rochester, NY 14623	585-334-5560	ROCHESTER	NY
Ohio			
BKC PAIN SPECIALISTS, LLC Principal place of business located at: 1065 Delaware Ave., Ste. A Marion, OH 43302 Registered Agent Address: Mark A. Peterson 2 Miranova Place, Ste. 330 Columbus, OH 43215	740-387-7246	MARION	OH
CINCINNATI PAIN MANAGEMENT Principal place of business located at: 8261 Cornell Rd., Ste. 630 Cincinnati, OH 45249	513-891-0022	CINCINNATI	OH
MARION PAIN CLINIC	740-375-0200	MARION	OH

Principal place of business located at: 1199 Delaware Ave. Marion, OH 43302			
ORTHO-SPINE REHABILITATION CENTER, INC. Principal place of business located at: 7211 Sawmill Road, Ste. 101 Dublin, OH 43016 Registered Agent Address: David L. Humphrey 7658 Slate Ridge Blvd. Reynoldsburg, OH 43068	614-793-8817	DUBLIN	OH
Pennsylvania			
ALLEGHENY PAIN MANAGEMENT Principal place of business located at: 1402 9th Ave. Altoona, PA 16602	814-940-2000	ALTOONA	PA
SOUTH HILLS PAIN & REHAB ASSOCIATES Principal place of business located at: 575 Coal Valley Rd. Jefferson Hills, PA 15025	412-469-7722	JEFFERSON HILLS	PA
Rhode Island			
NEW ENGLAND ANESTHESIOLOGY (NEA) Principal place of business located at: 22 Pasco Circle Warwick, RI 02886 Registered Agent Address: Stephen D. Zubiago, Esq. Nixon Peabody LLP One Citizens Plaza, Ste. 500 Providence, RI 02903	401-490-7530	WARWICK	RI
OCEAN STATE PAIN MANAGEMENT Principal place of business located at: 219 Cass Ave., Ste. A Woonsocket, RI 02895 Registered Agent Address: Abdul R. Barakat 6 Blackstone Valley Place, Unit 201 Lincoln, RI 02865	401-766-7700	WOONSOCKET	RI
OCEAN STATE PAIN MANAGEMENT Principal place of business located at: 219 Cass Ave., Ste. A Woonsocket, RI 02895	401-884-6070	EAST GREENWICH	RI

Registered Agent Address: Abdul R. Barakat 6 Blackstone Valley Place, Unit 201 Lincoln, RI 02865			
South Carolina			
INTERVENE MD Principal place of business located at: 1341 Old Georgetown Rd. Mt. Pleasant, SC 29464	843-216-4844	MOUNT PLEASANT	SC
Tennessee			
PCA PAIN CARE CENTER Total Healthcare Consultants, PLLC d/b/a Pain Care of Oak Ridge, now known as Comprehensive Pain Specialists, principal office and registered agent: Joy Day, 200 New York Ave #320, Oak Ridge, TN 37830 3024 Business Park Circle, Goodlettsville, TN 37072	865-835-5196	OAK RIDGE	TN
SPECIALTY SURGERY CENTER Principal place of business located at: 116 Brown Ave. Crossville, TN 38555 Registered Agent Address: Donathan M. Ivey 116 Brown Ave. Crossville, TN 38555	931-484-2500 x125	CROSSVILLE	TN
ST. THOMAS OUTPATIENT NEUROSURGICAL Principal place of business located at: 4230 Harding Pike, Floor 9 Nashville, TN 37205-2013 Registered Agent located at: 2011 Murphy Ave., Ste. 301 Nashville, TN 37203	615-341-3425	NASHVILLE	TN
Texas			
DALLAS BACK PAIN MANAGEMENT Principal place of business located at: 7515 Greenville Avenue, Ste. 505 Dallas, TX 75231	214-445-5077	DALLAS	TX
HARRIS METHODIST SOUTHLAKE CENTER Principal place of business located at: 1545 E. Southlake Blvd. Southlake, TX 76092	817-748-8778	SOUTHLAKE	TX

Virginia			
INSIGHT IMAGING-ROANOKE Principal place of business located at: 2923 Franklin Rd. SW Roanoke, VA 24014 Registered Agent Address: National Registered Agents, Inc. 4701 Cox Road, Ste. 285 Glen Allen, VA 23060	540-581-0882	ROANOKE	VA
NEW RIVER VALLEY SURGERY CENTER Principal place of business located at: 2901 Lamb Circle Christiansburg, VA 24073 Registered Agent Address: Tedd Puckett 2901 Lamb Circle Christiansburg, VA 24073	540-639-5888	CHRISTIANSBURG	VA
West Virginia			
PARS INTERVENTIONAL PAIN Principal place of business located at: 1212 Garfield Ave. Parkersburg, WV 26101	304-865-7277	PARKERSBURG	WV

23. The above-named hospitals, clinics and healthcare facilities, and their physicians, staff, agents and employees are collectively referred to herein as "Clinic Related Defendants" and may be named defendants in existing or subsequently filed complaints in this matter. At all relevant times, the physicians, staff, agents and employees of the above-named Clinic Related Defendants were acting within the course and scope of their employment and/or agency. The Clinic Related Defendants were responsible for procuring NECC Contaminated Drugs. Upon information and belief, the Clinic Related Defendants injected or administered the NECC Contaminated Drugs to Plaintiffs.

IV. FACTUAL BACKGROUND

A. The Conigliaro Family Businesses.

1. Conigliaro Industries' Recycling Plant.

24. In 1990, Gregory Conigliaro opened Conigliaro Engineering in an old industrial building on Waverly Street in Framingham, Massachusetts. In 1991, the company incorporated under the new name Conigliaro Industries, Inc. and began recycling plastic, metal, glass, and paper. It made money by converting detergent bottles into recycling bins, molded Styrofoam lunch trays into flower pots, and plastic computer casings into pothole filler.

25. Early on, Gregory Conigliaro branched out into real estate, starting GDC Holdings Inc. and GDC Properties Management LLC.

26. In April 2003, Conigliaro Industries opened the first U.S. commercial plant that shreds and recycles mattresses, including polyurethane foam parts. The mattress recycling operation was planned and developed by Tony Conigliaro, the Vice President of Engineering and Gregory's father. The company built a 2,500 square foot mattress shredding facility located next to its 90,000 square foot plant on a seven acre parcel in Framingham. The company also earmarked another 5,000 square feet of its main factory space for the venture and utilized its 30 docks for the operation.

27. Old used mattresses from schools, prisons, and hospitals are put through a giant shredder that separates the polyurethane foam from the springs and wood frame and bales the foam. Gregory Conigliaro claimed that the company (Nationwide Foam, Inc., 703 Waverly Street, Framingham, Massachusetts) could recycle mattresses at the rate of one each minute.

28. Today, Conigliaro Industries touts itself as a pioneer in the field of "Total Recycling" and recycles over 150 different materials, including rubber, plastics, and metal. The business operates out of an 88,000 square foot facility located at 701 Waverly Street, in the large Framingham complex owned by Gregory Conigliaro's real estate companies, GDC Holdings Inc. and/or GDC Properties Management LLC. The Framingham Board of Health has received a

number of complaints about the mounding trash piles tucked behind the Waverly Street strip mall.

Figure 1: Trash behind 701 Waverly Street[3]

Figure 2: Google Earth image of 701 Waverly St.

[3] "Sterility Found Lacking at Drug Site in Outbreak," N.Y. TIMES (Oct. 23, 2012) (available at http://www.nytimes.com/2012/10/24/health/sterility-found-lacking-at-drug-site-in-meningitis-outbreak.html?pagewanted=all&_r=0),.

2. Gregory Conigliaro, Barry Cadden, and Douglas Conigliaro founded NECC.

29. In 1998, well after the Conigliaro recycling facility and real estate companies were up and running, the Conigliaro family branched out into pharmaceutical compounding. Gregory Conigliaro's sister, Lisa Conigliaro Cadden, and her husband, Barry Cadden, were both pharmacists. Gregory Conigliaro and Barry Cadden co-founded New England Compounding Pharmacy, Inc., known as New England Compounding Center ("NECC"). NECC opened in the same Waverly Street building that housed the recycling plant and real estate businesses. Its front door is immediately next to the front door to Nationwide Foam.

30. Another Conigliaro brother, Dr. Douglas Conigliaro, was an anesthesiologist with substantial litigation in his past. He allegedly punctured a 64-year-old woman's spine during a 1995 operation to insert a pump to deliver painkillers. The woman became paralyzed and died two years later. The suit ultimately settled for $1 million and Douglas Conigliaro was fined $10,000 by the Florida state medical board.

31. Douglas Conigliaro's wife, Carla Conigliaro initially owned sixty-five percent (65%) of NECC. Carla Conigliaro (a nurse) was originally listed as the company's president. Douglas Conigliaro was personally involved with NECC from the beginning and continued to be involved until NECC shut its doors. Because of his previous legal troubles, he was careful to conceal his involvement. He also ordered others at NECC and the Affiliated Defendants to conceal his involvement.

32. Barry Cadden ran NECC, typically wearing scrubs to work. Cadden held positions as the President, Chief Pharmacist, and Director of NECC.

33. Gregory Conigliaro provided financial advice and usually wore a shirt and tie. Lisa Conigliaro Cadden was a board member and worked as a pharmacist at NECC.

34. According to former employees, Douglas Conigliaro was heavily involved in the day-to-day operations of NECC and Ameridose, though employees were told not to mention his involvement to potential clients or customers.

3. Medical Sales Management.

35. In or around 2002, the Conigliaros opened another company in the same Framingham building, called Medical Sales Management Inc. ("MSM"). MSM, led by Douglas Conigliaro, provided advertising and marketing services for NECC. As the sales arm for NECC and Ameridose, MSM promoted the compounding business at trade shows across the country, and its sales force aggressively worked the phones, cold-calling new customers and reaching out to existing ones. It also helped manage the company's computer operations.

36. Later, MSM provided the same services to Ameridose.

4. Ameridose.

37. In 2006, Gregory Conigliaro and Barry Cadden launched Ameridose, LLC ("Ameridose"), originally located in the same Framingham building. Former employees say the Conigliaro family found a new opportunity, selling a much-needed service to hospitals: prefilling syringes and breaking down vats of liquid medications into smaller intravenous bags for individual treatments. Historically hospitals did much of that work themselves. But new federal regulations required hospitals to go through more elaborate steps to handle sterile preparations, making it more costly and complicated.

38. Unlike NECC, Ameridose has a manufacturing license from the FDA, allowing it to ship medications in bulk without obtaining individual prescriptions.

39. Ameridose would later lease additional office space in Westborough, Massachusetts. This additional space was, in part, to accommodate the growing MSM sales force. Ameridose officially changed its address to the Westborough facility in 2011.

40. In 2008, Ameridose had 50 employees. As of 2012, that number had skyrocketed to 400. Ameridose is also currently under investigation for deficient and harmful product compounding and sterilization practices.

5. Alaunus Pharmaceutical.

41. In 2009, Gregory Conigliaro and Barry Cadden founded yet another company, Alaunus Pharmaceutical LLC. Alaunus identifies, develops, and markets generic pharmaceutical products to physicians and pharmacies throughout the United States. It has several Abbreviated New Drug Applications on file with the FDA though apparently no approved products. Alaunus is located at 687 Waverly Street, in the same office park as NECC and the recycling facility.

42. Figure 3: Waverly Business Center Sign[4]

B. Background on Compounding Pharmacies.

43. According to the FDA, traditional compounding is the extemporaneous combining, mixing, or altering of ingredients by a pharmacist in response to a physician's prescription to create a medication tailored to the specialized needs of an individual patient. Traditional compounding typically is used to prepare medications that are not available commercially, such as a drug for a patient who is allergic to an ingredient in a mass-produced product, or diluted dosages for children.

44. NECC's webpage claimed compounding allows doctors to prescribe prescription drugs that are "no longer manufactured, persistently backordered because of production shortages, not commercially available in the dosage form the patient needs (e.g., preservative free)."

[4] "Merging of families fueled business linked to meningitis outbreak," BOSTON GLOBE (Oct. 18, 2012) (available at http://www.nytimes.com/2012/10/24/health/sterility-found-lacking-at-drug-site-in-meningitis-outbreak.html?pagewanted=all&_r=0).

45. In Massachusetts, compounding pharmacies must have a prescription from an individual patient in order to create a drug.

46. Compounding pharmacies generally follow testing guidelines established by the U.S. Pharmacopeia (USP), a nonprofit private group that develops standards of drug quality. According to an industry group, the International Academy of Compounding Pharmacists, adherence to the USP standards is expected. Some Massachusetts compounding pharmacies, including Microtest Laboratories, typically test more than the number of samples required by the USP standards to confirm sterility.

47. Compounding industry standards were created for pharmacists making small batches of medicines for individuals, not for the commercial production of large batches.

C. The Risks of Pharmacy Compounding.

48. The serious risks of pharmacy compounding were the subject of considerable public discussion in the pharmacy community and the medical community before the subject meningitis outbreak.

49. In 2002, the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. The report concluded that "purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that . . . follows appropriate measures to ensure that injectable products are free of contamination."

50. On March 24, 2005, USA Today published a front page article with the following headline: "Safety concerns grow over pharmacy-mixed drugs." That article discussed growing concern over the fact that drugs produced in bulk by compounding pharmacies are not FDA approved and are not subject to the same oversight as drugs produced by pharmaceutical companies.

51. In 2006, the FDA conducted a survey of compounded drug products. They collected thirty-six samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey concluded "poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths."

52. In May 2007, the FDA published an article titled: "The Special Risks of Pharmacy Compounding." That article highlighted numerous adverse events involving compounded products. It also warned of the emergence of large scale compounding operations that were clearly operating outside the bounds of traditional compounding practice.

53. In 2010, the FDA posted an educational video on YouTube regarding concerns over the quality of compounded drugs.

54. On November 5, 2010, the American Society of Anesthesiologists, the American Society of Health-System Pharmacists ("ASHP") and other medical societies published a joint report regarding drug shortages. That report included an article written by the ASHP stating as follows:

> Compounding pharmacies have also pursued the production of drugs that are in short supply. Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards (e.g., United States Pharmacopeia chapter 797 or FDA labeling requirements). The sources of raw materials used by compounding pharmacies have been questioned, and apparent lapses in quality control have resulted in serious patient injury, including death.
>
> . . .
>
> Compounding pharmacies may also present patient risks; several deaths have been associated with improperly sterilized compounded products.

55. In May 2012, the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that "contamination of

compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products."

D. Meningitis.

56. Meningitis is an infection of the membranes covering the brain and spinal cord (meninges). Primary symptoms include: fever, chills, altered mental status, nausea, vomiting, sensitivity to light (photophobia), severe headache, and neck stiffness. Meningitis is typically diagnosed by lumbar puncture (spinal tap) that collects spinal fluid (cerebrospinal fluid). The fluid is then tested to determine the infection's exact cause for an appropriate course of treatment. When a lumbar puncture is not possible, a diagnosis may be presumed based on the constellation of symptoms. Complications and risks from meningitis include: brain damage, buildup of fluid between the skull and brain (subdural effusion), hearing loss, hydrocephalus, and seizures.

57. Meningitis can be caused by several factors including bacteria, viruses, and fungus. Fungal meningitis is rare and people with weak immune systems are at a higher risk of contraction.

58. Meningitis is an infection that usually spreads through the blood to the spinal cord. It is caused by the introduction of a bacteria, virus, or fungus into the central nervous system or from an infected body site next to the central nervous system. Primary symptoms include: fever, altered mental status, nausea, vomiting, sensitivity to light (photophobia), headache, and stiff neck. Death may result from fungal meningitis.

59. The typical incubation period for contracting fungal meningitis from a tainted steroid is one to four weeks after injection, though it can be far longer and symptoms can be mild in nature. As with any variety of meningitis, it is important to perform a lumbar puncture (spinal tap) to collect and test spinal fluid (cerebrospinal fluid) and determine the exact type of fungus

for an appropriate course of treatment. Appropriate laboratory tests may vary depending on the type of fungus suspected. Treatment of fungal meningitis typically requires long courses of high dose antifungal medications but treatment length can vary depending on the state of the immune system and type of fungus.

E. The Outbreak and Its Aftermath.

60. On September 21, 2012, the CDC was notified by the Tennessee Department of Health ("TDH") of a patient with the onset of meningitis following an epidural steroid injection. It was later determined that the patient had fungal meningitis.

61. On September 24, 2012 the TDH notified the Massachusetts Department of Public Health ("MDPH") about a cluster of six fungal meningitis cases with symptoms that began between July 30 and September 18, 2012. These patients all received injections of preservative free MPA, compounded at NECC in Framingham, Massachusetts.

62. In September 2012, the TDH identified nine cases of fungal meningitis following injection of MPA, compounded at NECC. All nine patients had received one or more injections from three lots of MPA (lot numbers 05212012@68, 06292012@26, and 08102012@51).

F. FDA and MDPH Begin Investigating NECC.

63. The MDPH, Board of Registration in Pharmacy, and Bureau of Infectious Diseases convened a multi-agency meeting with the TDH, the CDC, the FDA, and NECC. At the demand of MDPH staff, Barry Cadden and Gregory Conigliaro provided documentation of facilities that received medications from three lots of MPA suspected as linked to the fungal infections. According to those lists, the suspected lots contained 17,676 doses and were distributed to more than 14,000 patients in 23 states.

64. On September 26, 2012 NECC recalled three lots of preservative-free MPA: Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot

#08102012@51, BUD 2/6/2013. Approximately 3,000 doses were quarantined or returned through recall. This meant that approximately 14,000 people received contaminated injections. NECC faxed the recall notices to the facilities that had received the contaminated lots beginning on September 26, 2012.

65. On the same day, the MDPH began its investigation of NECC's facility. When MDPH arrived at NECC, investigators found NECC employees cleaning compounding areas and conducting environmental testing. The investigators also detected signs of black contamination in the compounding areas.

66. Before arrival of investigators, NECC had terminated many of its staff. After September 26, 2012, the majority of NECC employees were no longer on site.

67. On October 1, 2012 MDPH and FDA began a joint investigation of NECC. Investigators were shown examples of MPA products that were labeled as patient-specific. But NECC did not have individual prescriptions. Instead, it had lists of patients generated by clinical facilities and provided to NECC to obtain the product. NECC stated the list of names was considered to be an authorized prescription by the physician. This practice is not in accordance with Massachusetts regulations.

68. MDPH issued a formal Quarantine Notice pursuant to M.G.L. c. 94C §§13 and 189A, and M.G.L. c. 112 §§ 30 and 42A, in accordance with the CDC's epidemiological work. The Notice directs that all raw materials, all non-sterile and sterile products located at NECC used in the compounding of MPA and all inventory on the premises prepared for dispensing and stored at the pharmacy should be quarantined and not disposed of without MDPH's approval.

69. MDPH and FDA observed visible black particulate matter in sealed vials of purportedly sterile MPA returned to NECC. Inconsistencies in sterilization of processed

materials were identified through review of NECC's records. The board voted to obtain a Voluntary Surrender of NECC's license or to initiate action to issue a Temporary Order of Summary Suspension.

G. NECC Surrenders Its Pharmacy License and Recalls All of Its Products.

70. On October 3, 2012 NECC surrendered its pharmacy license. It ceased all production and initiated recall of all MPA and other drug products prepared for injections in and around the spinal cord (known as intrathecal administration).

71. On October 5, 2012 MDPH and FDA investigators noted visible contaminants in additional sealed recalled vials of MPA. MDPH and FDA issued a nationwide alert to providers and facilities across the country, informing them about the particulate matter.

72. On October 6, 2012 NECC, in conjunction with the FDA, CDC, and Massachusetts Board of Registration in Pharmacy's investigation, recalled all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts "due to the potential risk of contamination."

73. In NECC's October 6, 2012, press release, NECC advised that it was "notifying its customers of this recall by fax[,]" and that "[c]linics, hospitals and healthcare providers that have product which is being recalled should stop using the product immediately, retain and secure the product, and follow instructions contained in the fax notice."

H. FDA and Massachusetts Board of Pharmacy's Findings.

74. MDPH obtained documentary evidence (including photographs), reviewed and obtained copies of NECC Standard Operating Procedures, made observational findings, reviewed and obtained copies of all policies and procedures, reviewed batch records and interviewed NECC staff. The FDA conducted product testing and took environmental samples of various areas of the facility to test for contaminants.

75. From the beginning of their investigation, the MDPH and FDA identified "serious deficiencies and significant violations of pharmacy law and regulations that clearly placed the public's health and safety at risk." The FDA reported that it had detected fungal contamination by microscopic examination of particulate matter taken from a sealed vial of MPA collected from NECC. The FDA also noted that "foreign material" had also been observed in other vials produced by NECC that were collected by FDA during an inspection. FDA further stated that it was in the process of further identifying the fungal contaminant and conducting microbial testing.

I. MDPH's Preliminary Findings.

76. On October 23, 2012, the MDPH released its preliminary investigation findings. A copy of the report is attached as Exhibit A.

77. NECC distributed two of the recalled lots of MPA (preservative free) 80 MG/ML before receiving results of sterility testing. Lot 06292012@26 was prepared on June 29, 2012. Final sterility testing was completed on July 17, 2012. Two shipments of product were sent out before the final sterility tests results were received. Lot 08102012@51 was prepared on August 10, 2012. Final sterility testing was completed on August 28, 2012. At least eleven shipments of product were sent out before the final sterility test results were received. NECC's records claim that these sterility tests found no contamination, but the MDPH questioned whether NECC's sterility testing methods were adequate.

78. The MDPH observed visible black particulate matter in several recalled sealed vials of MPA from Lot 08102012@51.

79. NECC did not follow either the proper USP 797 autoclaving sterilization procedure or its own standard operating procedures. The MDPH noted NECC's systemic failure

to keep products in the autoclave for the required minimum 20-minute sterilization period necessary to ensure product sterility.

80. MDPH found that NECC distributed large batches of compound "sterile" products directly to facilities apparently for general use rather than requiring a prescription for an individual patient, in violation of its state pharmacy license.

81. NECC did not have patient-specific prescriptions from an authorized practitioner when compounding and dispensing medication, as required by state law.

82. NECC did not conduct patient-specific medication history and drug utilization reviews, as required by regulations.

83. The clean rooms used to compound the drugs were not appropriately sealed, allowing contaminants to infiltrate the room, and exposing the drugs to contamination.

84. Powder hoods, intended to protect pharmacists from inhaling substances during medication preparation. within the sterile compounding area were not thoroughly cleaned pursuant to USP 797 or pursuant to NECC standard operating procedures. Residual powder was visually observed, which could lead to contamination of compounded medications.

85. "Tacky mats" used to trap dirt, dust, and other potential contaminants from shoes prior to clean room entry were visibly soiled with debris, in violation of USP 797.

86. A leaky boiler next to the clean room created an environment susceptible to contaminant growth, including a pool of standing water.

J. FDA's Initial Findings and Form 483 Report.

87. On October 18, 2012, the FDA released definitive laboratory confirmation of the presences of fungal contaminants in sealed vials of MPA in a suspect lot prepared by NECC.

88. On October 26, 2012, the FDA released a copy of the FDA form 483 issued to NECC. The FDA issues a 483 at the end of an inspection when the investigators believe that

they observed conditions or practices that indicate violations of the Food, Drug, and Cosmetic Act or attendant regulations. A copy of the report is attached as Exhibit B.

89. The FDA observed and has since confirmed contaminated products and listed a number of observations regarding conditions in the Clean Room 2 at NECC's Framingham facility.

90. During an October 2, 2012 inspection, the FDA observed that approximately 83 vials of a bin of 321 vials of MPA from Lot #08102012@51 (shipped between August 17, 2012 and September 25, 2012) contained a greenish black foreign matter. Seventeen vials from the same bin contained white filamentous material.

91. The FDA's sterility analysis of a sample confirmed the presence of "viable microbial growth" in all of the 50 vials tested. One vial showed fungal morphological features.

92. The FDA reported that NECC's formula worksheets state that the raw materials used to create their drug products are sterile. NECC's pharmacy director told the FDA that NECC uses non-sterile active pharmaceutical ingredients (API) and non-sterile raw materials to formulate preservative free MPA, triamcinolone, and other injectable suspensions. The inspection confirmed that the labeling for the MPA API and other raw materials did not indicate that they were sterile.

93. NECC claimed that its "steam autoclave cycle" "sterilized" suspensions formulated with non-sterile materials. The FDA noted that NECC provided no documentation or evidence that this autoclave procedure worked. In fact, the FDA reported tarnish, condensation, and discoloration in the autoclaves. The FDA also observed puddles of water in the base of the autoclave chamber.

94. The FDA also reported that on at least 26 occasions between January 2012 and September 2012, NECC's internal environmental monitoring program recorded bacteria and mold in the clean rooms used to produce "sterile" drug products. This included at least 38 instances where the level of bacteria recorded was above the level where NECC was supposed to take action ("action level" or "action limit") and 18 instances where the level of mold reported was above NECC's action level. According to the FDA's director of manufacturing and product quality, an action limit is a threshold measurement of contamination "above what would typically be seen in a controlled sterile environment." Yet NECC took no action to investigate or correct this bacterial and mold contamination:

> There was no investigation conducted by the firm when levels exceeded their action limits and there was no identification of the isolates. No documented corrective actions were taken to remove the microbial contamination (bacteria and mold) from the facility.

95. Some of the petri dishes used to grow microbes present in environmental samples taken from windowsills, equipment, furniture, floors and other surfaces were "overflowing" with bacteria or fungi in sheets "very visible to the naked eye." The FDA also reported that samples taken from inside the hoods used for compounding (also inside the ostensibly clean rooms) between January and September 2012 showed at least eight instances of bacterial and/or mold contamination. NECC did not investigate this contamination, did not identify the types of mold or bacteria growing in their ostensibly sterile hoods, nor investigate the impact of this contamination on any of the purportedly sterile products made in the hoods on the days the samples were taken. "[NECC] has no evidence that any corrective actions were taken to prevent contamination of the sterile drug products."

96. The FDA also observed that a plastic and mattress recycling facility next door produced dust and other airborne contaminants. NECC's HVAC units on the roof were about

100 feet from the recycling facility. Inside NECC, the FDA observed that dark particulate and white, filamentous substances covered the louvers of an HVAC return located behind the autoclave in the clean room.

97. The FDA also observed that the air-conditioning in the clean rooms was turned off overnight. This is not typical for a clean room, as temperatures need to be kept constant to minimize microbial growth.

98. The FDA also observed that a boiler located within 30 feet of the entrance to one of the "Prep Room" was leaking water into puddles. The wet floor around the boiler was soiled with thick white debris and thick black granular material.

99. The mat at the entrance of the Prep Room was brown and soiled. In other words, it was filthy.

100. The FDA also observed cloudy discoloration on the barrier facing the ISO 6 Clean Room and metal surfaces of the pass through in the wall to the ISO 6 Clean Room. The metal ledge within the clean room contained reddish-brown and cloudy substances. And there were "dark, hair like discoloration" along the gasket and crevices located at the bottom edge of the closed pass through installed within the wall of the ISO 6 Clean Room. NECC used the ISO 6 Clean Room to formulate and fill sterile preparation, including MPA.

K. The Investigation Grows, Covering Other Drugs and Related Corporate Entities.

1. MDPH Shuts Down Ameridose and Suspends Insiders' Pharmacy Licenses.

101. On October 8, 2012, at the MDPH and FDA's insistence, Barry Cadden, Glenn Chin, and Lisa Cadden, leaders at NECC, agreed to stop practicing as pharmacists until the investigation was complete. On October 10, 2012 MDPH asked Ameridose and Alaunus Pharmaceuticals to cease all operations, including dispensing, manufacturing, or distributing any

products. MDPH demanded that Barry Cadden immediately resign as manager, director and from any other management position at NECC, or Ameridose.

2. FDA Confirms Other NECC Products Are Contaminated.

102. On October 15, 2012 the FDA issued an advisory that a patient may have acquired fungal meningitis from a different steroid injection, triamcinolone acetonide. In addition, the FDA reported a transplant patient with aspergillus fumigatus infection who received NECC cardioplegic solution during surgery. MDPH asked Massachusetts providers to contact any patients who received any injectable product, including ophthalmic drugs or cardioplegia solutions prepared by NECC after May 21, 2012.

103. On October 18, 2012 *t*he FDA confirmed the presence of fungal contaminates in sealed vials of MPA in a suspect lot prepared by NECC. The FDA also collected samples from sealed vials of completed product at Ameridose.

3. Board of Pharmacy Revokes Cadden, Chin and Conigliaro Pharmacy Licenses.

104. On October 22, 2012 *t*he Board of Pharmacy and MDPH announced that Barry J. Cadden, Glenn A Chin, and Lisa Conigliaro Cadden are prevented from practicing as pharmacists, that it asked all three to surrender their pharmacist licenses immediately, and that if they did not voluntarily comply their license would be permanently revoked. According to MDPH, "[i]f the three pharmacists and NECC do not comply, the Board authorized staff to proceed with permanent revocation."

L. FDA and MDPH Investigate Ameridose and Alaunus Pharmaceuticals.

105. On October 19, 2012 investigators at MDPH and FDA scrutinized the business practices of Alaunus Pharmaceuticals and potential for inappropriate distribution of NECC or Ameridose products.

106. On October 31, 2012 Ameridose announced a recall of all of its products. The company sells more than 2,200 drugs in syringes (injectable and oral) and intravenous medicine bags.

107. Dr. Janet Woodcock, the director of the Center for Drug Evaluation and Research at the FDA, said in a telephone interview that the company offered to recall all of its products after federal officials shared the results of their inspection, which found fault with some of its sterility "assurances."

108. On November 1, 2012 the FDA and CDC found bacterial contamination in two other drugs made by NECC, preservative-free betamethasone (a steroid used to help back pain) and cardioplegia solution (used during heart surgery). The FDA found bacteria in three separate batches of betamethasone. Earlier tests had found fungal contamination in the cardioplegia solution. These findings "reinforce the FDA's concern about the lack of sterility in products produced at NECC's compounding facility and serve to underscore that hospitals, clinics, and health care providers should not use any NECC-supplied products."

1. FDA Confirms Ameridose's Products Are Contaminated.

109. On November 9, 2012, the FDA released a report describing the results of its inspection of the Ameridose facilities at 701 and 705 Flanders Road in Westborough, MA. The dates of inspection included October 10-12, October 15-16, October 18-19, October 22-23, October 26, and November 6-9. A copy of the report is attached as Exhibit C.

110. The report made 15 observations. Two of these observations were "repeat items" included in an FDA form 483 report issued to Ameridose on August 6, 2008. Namely, that (1) Ameridose does not test the potency of its final drug products before releasing them for distribution (despite receiving 33 complaints about lack of effect) and (2) Ameridose does not test final units of finished product lots for sterility and the presence of bacterial endotoxin.

111. The FDA observed that Ameridose failed to investigate microbial contamination observed at least fifty three (53) times during sterility testing of stock solutions intended to be used in the manufacture of sterile injectable products, including lots of Fentanyl, Ropivacain, and morphine. Multiple lots of purportedly sterile injectable drug products were compounded, prepared, sold, and distributed from these contaminated lots.

112. The FDA saw "no documented evidence" to suggest that Ameridose ever conducted a health hazard investigation of these 53 instances of contamination. Ameridose claimed that these sterility failures were attributed to contamination during the sterility testing itself (as opposed to during the manufacture of the product); the FDA noted that there was "no data to support" this claim.

113. Ameridose regularly disregarded sterility test results that were "positive," meaning that test results showed products were contaminated and/or not sterile. Ameridose assumed that any positive result was "inconclusive" or "suspect" and re-ran the test. This re-testing often revealed more non-sterile units than the original test. Ameridose did nothing to identify the source of the contamination or subculture the bacteria to determine its identity.

114. In 2012, forty-five (45) environmental microbiological contaminants, bacterial and mold, were found in "critical areas," including instances of employees' presumably uncovered fingers inside on the hoods and controlled manufacturing areas during the manufacture of purportedly sterile drug products. There is no evidence that Ameridose took any steps to assess the potential quality impact of these potential contaminates. On at least one occasion, Ameridose "re-filtered" sterile stock solutions involved in the sterility failure and then released the final drug products for patient use.

115. Ameridose received at least 29 adverse event reports associated with its products. These ranged from reports of low potency, post-partum hemorrhaging, over-sedation, respiratory distress, and lack of effect. Ameridose did not report any of these adverse events to the FDA, as required by law. Instead, Ameridose called these "patient responses" or "non-complaints" and did not investigate or failed to investigate what the FDA called "a trend of complaints."

116. The FDA also observed visible indications of deficient manufacturing conditions. Gowns, eye-protection, and gloves worn by employees were not sterile and were reused multiple times before being sent for cleaning. Ameridose failed to perform environmental monitoring of the hoods used to manufacture products. "Penetrating leaks" were observed in the roof above the clean room; Ameridose used totes to catch the streaming rain water. Walls in a room used to prepare purportedly sterile drug products were cracked, corroded, and covered with a sticky material. "Brownish structures," "whitish, opaque structures," rust, broken glass, "foreign material" and "thick residues" that were orange, brown, and green were found in and around the metal hoods used to prepare drug products. All of these hoods were indicated to be "clean and available for processing."

117. Ameridose did not evaluate any alarms reported by their air handling system.

118. Perhaps most disturbingly, the FDA reported insect infestations within 3-10 feet of the controlled area where sterile products were made. And at least one bird flew through an area where sterile finished product is packaged and stored during the FDA's investigation.

M. Criminal and Congressional Investigations.

119. The Department of Justice and the Commonwealth of Massachusetts have announced that they are pursuing criminal investigations of NECC's practices. Other States' Attorney Generals are also pursuing criminal investigations, including Michigan's, the state that has the most reported deaths and illnesses linked to NECC's Contaminated Drugs.

120. The U.S. House of Representatives Energy and Commerce Committee is also investigating the outbreak; in particular, the history of investigations and operation at NECC and other companies Barry Cadden was affiliated with that were at any point involved in the production, sale, and/or distribution of drug products. On October 11, 2012, the Committee wrote to Barry Cadden individually to request that NECC preserve all relevant documents and communications and that NECC make arrangements with Committee staff to testify before the Committee before October 18, 2012. Neither Cadden nor anyone else from NECC made themselves available to brief the committee.

121. On October, 22, 2012, the Committee asked Cadden to provide documents from January 1, 2002 through the present , including:

> All documents containing communications referring to relating to any license or inspection of the NECC, Ameridose, and/or Alaunus that [Cadden] sent or received using a personal email account;
>
> All documents containing communications referring or relating to the scope of business conducted by the NECC, Ameridose, and/or Alaunus that you sent or received using a personal email account;
>
> All documents containing communications referring or relating to any safety and/or quality issue related to any product produced, sold, and/or distributed by NECC, Ameridose, and/or Alaunus that you sent or received using a personal email account.

122. On November 14, 2012, the Committee held a hearing, titled "The Fungal Meningitis Outbreak: Could It Have Been Prevented?" Barry Cadden appeared, but repeatedly asserted his Fifth Amendment right against self-incrimination and did not answer any of the Committee's substantive questions.

N. Subsequent Litigation.

123. Lawsuits alleging death or injury based on contaminated MPA and other contaminated drugs have been filed around the country. On February 12, 2013, the Judicial

Panel on Multidistrict Litigation issued an order under 28 U.S.C. § 1407 transferring various federal court proceedings to the United States District Court for the District of Massachusetts for coordinated pretrial proceedings.

O. Current Case Counts.

124. As of November 3, 2013, the CDC reports 751 cases of fungal meningitis, stroke due to presumed fungal meningitis, or other central nervous system-related infection meeting the outbreak case definition, in addition to paraspinal/spinal joint infections and peripheral joint infections (e.g., knee, hip, shoulder, and elbow). The CDC reports cases in Florida, Georgia, Idaho, Illinois, Indiana, Maryland, Michigan, Minnesota, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, and Virginia. Of these 751 reported cases of fungal meningitis, at least 64 people have died (in nine different states). The CDC estimates that at least 14,000 patients were administered injections from just the three recalled lots of methylprednisolone acetate.

V. FACTUAL ALLEGATIONS

A. Liberty Industries, Inc.

125. Liberty is a designer, manufacturer, distributor and installer of cleanrooms and contamination control supplies both in the United States and worldwide.

126. In 2005, 2006 and 2008, Liberty manufactured, constructed, installed, and/or designed an ISO Class 7, ISO Class 6, and an ISO Class 5 cleanroom ("the Cleanrooms"), respectively, for NECC and/or Ameridose at the Framingham, Massachusetts facility.

127. Upon information and belief, subsequent room additions, rework or repair (warranty or otherwise), and/or system upgrades, done by Liberty, took place within each of these Cleanrooms after certification had been issued.

128. The Cleanrooms manufactured, constructed, installed and/or designed for NECC/Ameridose contained defects that made them unsuitable for their intended use. Liberty owed a duty to Plaintiffs, to manufacture, construct, install, and/or design the NECC/Ameridose Cleanrooms in such a manner as to prevent the contamination of pharmaceuticals compounded within them.

129. Liberty knew, or reasonably should have known, that the Cleanrooms were defective upon certifying them ready to use and/or upon inspecting the premises after certification and/or upon subsequent addition, rework or repair of the Cleanrooms.

130. Upon further information and belief, one or more of the Cleanrooms was designed with, manufactured, constructed and/or had installed faulty ceiling grids and/or used improper materials in addition to other deficiencies creating a cleanroom environment prone to pressure inconsistencies, water damage and other failings that would disrupt or destroy the cleanliness of the Cleanrooms and making them susceptible to contamination.

131. Upon information and belief, on numerous occasions, NECC requested and was denied repair of Liberty's defective work. In at least one cleanroom designed and installed by Liberty, a large opening in the wall provided access to a conveyor belt covered only with hanging vinyl slats. This opening provided a means of potential contamination and made it difficult to maintain the required negative air pressure.

132. Further, upon information and belief, Liberty had actual and/or constructive knowledge of the deficiencies in the design, manufacture, construction, and installation of the Cleanrooms, such that products compounded within them were subject to contamination.

133. One or more of the Cleanrooms were used to compound the NECC Contaminated Drugs administered to Plaintiffs.

134. The defective manufacture, construction, installation, and/or design of the Cleanrooms, and Liberty's failure to remedy the defects despite its actual and/or constructive knowledge of those deficiencies, caused Plaintiffs to suffer damages, including, but not limited to, expenses associated with the treatment of fungal meningitis and other illnesses. The defects were the direct, proximate, and foreseeable cause of damages incurred by Plaintiffs.

135. Had Liberty exercised its duty to exercise reasonable conduct by properly manufacturing, designing, and certifying the Cleanrooms, Plaintiffs would not have suffered the damages complained of herein.

B. UniFirst Corporation.

136. UniClean Cleanroom Services ("UniClean") is a division of Defendant UniFirst Corporation. Hereafter the entity shall be referred to as "UniFirst." UniFirst holds itself out as a service provider delivering value-added services and products to, among other industries, the medical device, pharmaceutical, and other industries that utilize cleanroom controlled environments. UniFirst represents that it offers comprehensive cleanroom cleaning and maintenance programs to help ensure that facilities are operating within specified classification goals.

137. UniFirst itself and/or through UniClean, touts its expertise to companies like NECC and Ameridose. UniFirst knows that particulates in cleanrooms are deposited onto surfaces such as floors, walls, work surfaces and machinery, and that these particulates may cause increases in manufacturing and product compounding reject rates. UniFirst, its agents, employees, representatives, and UniClean workers have, for many years, had actual knowledge that visible and non-visible particulate loads can also lead to product contamination safety concerns for end users. In its marketing materials Unifirst acknowledges that to reduce these risks, it is imperative that an effective cleanroom cleaning program be implemented and

maintained. UniFirst claims to follow stringent cleaning procedures and claims to employ highly-trained technicians as key components in eliminating such contamination threats.

138. At all times mentioned herein and material hereto, UniFirst held itself and its agents, servants, workers, representatives, personnel, and employees out to be skillful and qualified to deliver quality services and products and through the highest standards. Indeed, UniFirst itself and/or UniClean, represents that it is an ISO 9001: 2008 registered company offering services that include sterile and non-sterile garment services, and contamination control including cleanroom cleaning, fogging and environmental monitoring, among other services.

139. UniFirst recognizes the dangers associated with contaminated cleanrooms. In the company's own marketing materials, it acknowledges that "80% of the dirt and grime that enters your building is tracked in on the shoes of employees and visitors." UniFirst knows that any contract for services or products entered into with any company such as NECC or Ameridose has a direct benefit for customers, who are the intended beneficiaries of such contracts. For example, UniFirst has stated on its website and in marketing materials that over 70% of customers say that a poorly maintained facility "is enough reason not to patronize a business again," and that by hiring UniFirst, a company's "business image will remain spotless, and your customers and employees will know you care."

140. UniFirst markets its products and services aggressively, and represents that, among other things, "To help with your infection control efforts, UniFirst delivers fresh mops and wipers and picks up your soiled ones on a regular schedule. We maintain inventory, perform hygienic laundering, and replace any worn out items."

141. UniFirst entered into a Contamination Control Service Agreement ("CCSA") with NECC on October 7, 2008, and renewed it thereafter, such that a contract existed in calendar years 2011 and 2012.

142. According to the terms of the CCSA and later iterations, UniFirst agreed to furnish services with supporting materials necessary for the performance of its duties, which expressly included cleaning each Cleanroom at the NECC facilities. UniFirst's duties were outlined in a Service Schedule attached and incorporated into the CCSA first signed and thereafter in force and effect. UniFirst's duties included cleaning and sanitizing each anteroom and cleanroom. The areas to be cleaned and sanitized by UniFirst employees included but were not limited to the floors, ceilings, and hoods of each room. UniFirst agreed to a triple decontamination process for each room, using products provided by UniFirst.

143. UniFirst agreed that, among other things, it would specifically provide its staff with cleanroom training and training regarding NECC's Standard Operating Procedures.

144. UniFirst performed services and sold products to NECC each month, from calendar year 2010 through September 2012, and UniFirst invoiced NECC for services rendered.

145. During the stated time frame, UniFirst failed to meets its own written standards in performing its contractual duties, allowing the contamination of the cleanrooms UniFirst was entrusted to clean in the following ways: (A) UniFirst employees, contractors and/or representatives, including those within the UniClean division, entered the NECC facilities (including the anterooms) in street clothes, without donning sterile or contaminant-free such as shoe covers, hair caps, coveralls, and gloves that were readily available at the NECC facilities; (B) UniFirst employees, contractors and/or representatives brought into the NECC anterooms and cleanrooms cleaning equipment, including mops, mop heads, sponges and buckets that had

been moved through exterior environments, even though such equipment had not been sanitized by or cleaned appropriately, allowing contamination to occur throughout various parts of the NECC facility; and (C) UniFirst employees, contractors and/or representatives failed to clean or wipe shoes, boots and other footwear on floor mats used in the room entry process, thereby allowing contaminants into and throughout the NECC facility.

146. UniFirst had actual knowledge of the dangers of bacteria, mold and other microorganisms. UniFirst knew or should have known that such contaminants - if not eliminated - would expose patients and end use consumers such as Plaintiffs, to contamination of products produced by NECC in its cleanrooms.

147. UniFirst had actual knowledge of the very mold that was ultimately found in the NECC facility. In a "white paper" found on the www.unifirst.com website, UniFirst identifies aspergillus niger as a "mold" that grows when garments are contaminated. In the white paper UniFirst acknowledges that this mold represents one of the most common types of microorganism contaminants found in facilities like the NECC location.

148. Aspergillus niger was found or brought into the NECC facility. UniFirst failed to perform the job it was hired to do.

149. As a result of failures and omissions, UniFirst (solely or in concert with NECC) negligently allowed contaminants such as aspergillus into every cleanroom where recalled products were made, composed, mixed, prepared, packaged and stored.

150. UniFirst, its agents, and employees knew or should have known of the dangers of allowing contaminants into the NECC facility, including its anterooms and cleanrooms. UniFirst did not conduct appropriate due diligence to follow its own policies and procedures, and failed to follow NECC policies and procedures when in that facility.

C. Clinics, Hospitals, and Physicians.

151. The Plaintiffs sought treatment from the Clinic Related Defendants.

152. The Clinic Related Defendants and their employees, affiliates, and agents owed Plaintiffs numerous duties including, without limitation, the following: to act as reasonable and prudent healthcare providers; and to ensure that the medical treatment, including drugs, that they administered to patients, including Plaintiffs, were safe and effective.

153. As part of this medical treatment, the Clinic Related Defendants administered NECC contaminated drugs, and/or NECC drugs suspected to be contaminated, to the Plaintiffs.

154. In many instances, the Clinic Related Defendants injected MPA directly into patients', including Plaintiffs' spinal canals, so as to enter the central nervous system, bypassing many or all of the body's natural defensive mechanisms.

155. The Clinic Related Defendants knew, or should have known, that the central nervous system is a relatively closed system, making treatment options more difficult in the event of an adulterated invasion.

156. The Clinic Related Defendants knew, or should have known, that the MPA they purchased acts as an immune system-suppressing agent, thus weakening the patient's, including Plaintiffs', natural ability to fight off pathogens that could possibly be included in the injection.

157. The Clinic Related Defendants knew, or should have known, the importance of purchasing and administering safe and effective drugs to their patients, including Plaintiffs.

158. The Clinic Related Defendants knew, or should have known, that one of the best ways of ensuring that it injects safe and effective drugs directly into the spinal canals, and other vulnerable places, of their patients was to use only drugs approved by the FDA for the intended form of administration.

159. The use of NECC's drugs administered to the Plaintiffs has not been approved by the FDA.

160. The Clinic Related Defendants knew, or should have known, that NECC's drugs that it administered to the Plaintiffs had not been approved by the FDA.

161. The Clinic Related Defendants knew, or should have known, that another way of ensuring that they administered safe and effective drugs directly into, for example, the spinal canals of their patients, was to purchase such drugs from an FDA-regulated manufacturer.

162. The Clinic Related Defendants knew, or should have known, that NECC was not an FDA approved manufacturer.

163. NECC's un-regulated drugs were used by the Clinic Related Defendants in lieu of commercially available drug products manufactured by FDA-regulated manufacturers.

164. Although NECC operated in Massachusetts, it was also required to comply with the laws of the states of the Clinic Related Defendants.

165. It is a violation of the laws of the states of many of the Clinic Related Defendants, to sell compounded drugs in bulk and without a patient-specific prescription. NECC violated these laws.

166. Rather than producing small quantities of its drugs on a per-prescription basis, NECC engaged in the illegal and risky process of producing and marketing very large quantities of its drugs at one time and not per prescription as required by the law of many of the Clinic Related Defendants' states.

167. The Clinic Related Defendants knew, or should have known, that NECC engaged in the process of producing and marketing very large quantities of its drugs.

168. Under the law of the states of the Clinic Related Defendants, corporations like NECC located outside their states who engage in the wholesale distribution of prescription drugs into their states must register with those states.

169. NECC acted as a wholesale distributor by selling very large quantities of its drugs to the Clinic Related Defendants.

170. The Clinic Related Defendants knew, or should have known, that NECC acted as a wholesale distributor by selling large quantities of its drugs to them, without being registered to do so within their states.

171. The Clinic Related Defendants knew, or should have known, that NECC was not registered to distribute prescription drugs wholesale in their state.

172. NECC engaged in the large-scale production and sale of its drugs without individual prescriptions in violation of the law of many of the states of the Clinic Related Defendants.

173. The Clinic Related Defendants knew, or should have known, that NECC engaged in the large-scale production and sale of its drugs without individual prescriptions in violation of state laws.

174. Notwithstanding the foregoing knowledge, many, if not all, of the Clinic Related Defendants voluntarily purchased drugs for use on the Plaintiffs on a wholesale basis from NECC without prescriptions.

175. Many, if not all, of the Clinic Related Defendants provided patient lists to NECC even though the patients on the lists did not necessarily receive the drug. Often times, the lists provided to NECC by the Clinic Related Defendants included false patient names.

176. By providing a list of names of patients who were not necessarily going to receive the drug, and certainly providing false names, the Clinic Related Defendants conspired with NECC, ignoring patient safety.

177. Under the laws of the states of the Clinic Related Defendants, compounding pharmacists must ensure compliance with USP-NF standards (United States Pharmacopeia National Formulary).

178. NECC and its pharmacists did not comply with USP-NF standards.

179. The Clinic Related Defendants knew, or should have known, that NECC was not compliant with USP-NF standards.

180. The Clinic Related Defendants knew, or should have known, that another way of ensuring that safe and effective drugs are administered to their patients, including the Plaintiffs, was to purchase such drugs from an accredited compounding pharmacy or purchase pharmaceuticals directly from pharmaceutical manufacturers regulated by the FDA.

181. NECC is not, and at all relevant times was not, accredited by the Pharmacy Compounding Accreditation Board ("PCAB") or any other similar organization, such as The Joint Commission, that offer independent assurance as to the quality and competence of compounding pharmacies that meet certain requirements.

182. The Clinic Related Defendants knew, or should have known, that NECC was not an accredited compounding pharmacy.

183. There are accredited compounding pharmacies throughout the United States, and at times, in the Clinic Related Defendants' own state, but the Clinic Related Defendants chose not to purchase drugs from them, electing instead to buy drugs from an unaccredited, unregistered wholesale pharmacy for use in treating Plaintiffs.

184. The Clinic Related Defendants knew, or should have known, that another way of ensuring that safe and effective steroids are administered to their patients was to purchase drugs which contain preservatives.

185. The hazards, dangers and problems entailed in administering compounded drugs, and especially the use of preservative free sterile preparations, were well known to the medical profession, including the Clinic Related Defendants, and the subject of many articles and professional guidance documents.

186. NECC produced MPA, and other drugs administered to the Plaintiffs, without preservatives.

187. The Clinic Related Defendants knew, or should have known, that NECC produced drugs they administered to the Plaintiffs without preservatives.

188. The Clinic Related Defendants knew or should have known that purchasing and utilizing preservative free products, as was done here, increased the risk of contamination. Because the vials contained no antimicrobial preservative, there was nothing to inhibit the growth of bacteria and fungus that were introduced into the drugs administered to the Plaintiffs by the Clinic Related Defendants.

189. Despite the increased risk of using preservative free drugs, and of purchasing drugs not approved by the FDA, the Clinic Related Defendants purchased the drugs it administered to the Plaintiffs from un-accredited NECC for use in the most vulnerable areas of the Plaintiffs' bodies.

190. The Clinic Related Defendants knew, or should have known, that another way of ensuring that safe and effective drugs are administered to their patients, including the Plaintiffs,

was to ensure that such drugs are produced to the highest standards, including in a highly sterile environment.

191. While NECC is not regulated by the FDA, the American Society of Health-System Pharmacists (ASHP) has published *Guidelines on Outsourcing Sterile Compounding Services* (herein after Outsourcing Compounding Guidelines). At all relevant times, the Clinic Related Defendants were subject to the Outsourcing Compounding Guidelines.

192. At all times relevant, the Clinic Related Defendants failed to perform the following due diligence prior to purchasing sterile compounds from NECC, as recommended by the ASHP *Guidelines on Outsourcing Sterile Compounding Services*, including, but not limited to:

a. verify whether NECC's quality processes demonstrated that NECC was a reputable and safe supplier of sterile injectable compounds;

b. determine if NECC was an accredited compounding pharmacy;

c. at least once annually, unannounced, visit NECC's corporate offices and compounding facilities and confer with NECC's corporate, pharmacy and compounding staff;

d. determine whether NECC had any product liability lawsuits filed against it for preparations compounded;

e. determine whether there had ever been recalls of any of NECC's compounded preparations;

f. evaluate NECC's standard operating procedures and manuals;

g. evaluate NECC's pharmacist technician training;

h. evaluate NECC's policies and procedures for sterility testing;

i. evaluate examples of batch reports for product being considered for outsourcing;

j. evaluate examples of quality-control reports;

k. obtain and evaluate history of the results of all NECC accreditation or regulatory surveys conducted of NECC's sites, including copies of significant regulatory actions;

l. determine if NECC could provide documentation of the end-product testing processes used to determine that compounded sterile preparations are sterile and free of pyrogens and unintended particulate matter;

m. evaluate whether NECC could assure that each compounded sterile preparation was sterile and free of pyrogens and unintended particulate matter according to professional established and accepted quality monitoring data;

n. determine whether NECC performed nonviable and viable particle testing in primary engineering controls (e.g., laminar flow workbench, biological safety cabinet) and room air according to USP chapter 797 standards;

o. determine whether NECC performed routine surface microbiological and fungal environmental monitoring to minimize contamination;

p. determine whether NECC had a policy that required validation of new or changed facilities, equipment, processes, container types, for sterility and repeatability;

q. determine whether NECC met ASHP, NIOSH and USP chapter 797 guidelines for the handling of hazardous agents;

r. evaluate NECC's quality management program, specifically as it relates to facility cleaning and validation, staff training, and competency assessment;

s. evaluate NECC's risk assessment program to ensure that medication errors are not introduced by new or increased outsourced compounding activities; and

t. determine whether NECC had a history of disciplinary or punitive actions by any regulatory agency.

193. Upon information and belief, had the Clinic Related Defendants followed the recommendations set forth in the Outsourcing Compounding Guidelines, it would have found NECC in the deplorable conditions set forth above, learned of its unsuitable, checkered history, prior reprimands, and problems and complaints related to their practices and products.

194. Despite the importance of the sterile nature of the drugs the Clinic Related Defendants administered to Plaintiffs, NECC's facility and production processes were unsanitary and unsterile, and lacked adequate quality control measures.

195. The Clinic Related Defendants knew, or should have known, that NECC's drugs and production processes were unsanitary and unsterile, and lacked adequate quality control measures.

196. NECC took large quantities of non-sterile ingredients and placed them into an aqueous mixture that then had to be rendered sterile.

197. NECC's process made its drugs unreasonably dangerous, high risk compounds.

198. NECC competed in the medical marketplace on the basis of offering cheaper prices. Upon information and belief, NECC's cheaper pricing was a major factor in the Clinic Related Defendants' decisions to purchase drugs from NECC, as opposed to from other FDA-regulated manufacturers of approved drugs.

199. Despite what the Clinic Related Defendants knew, or should have known, concerning NECC, they chose to purchase the drugs they administered to the Plaintiffs from NECC, which was an unaccredited, unsafe compounding pharmacy that: (a) produced its drugs in the same complex as a waste facility; (b) produced the drugs in bulk batches; (c) did not properly sterilize the drugs; (d) did not operate with adequate quality control measures; (e) did not operate in a sterile environment; (f) did not have adequately representative samples of the drugs independently tested by an FDA-approved testing facility before releasing them for distribution; (g) did not comply with USP-NF standards; (h) violated several provisions of the states of the Clinic Related Defendants law designed to protect their citizens from substandard

and adulterated prescription drugs; and (i) contracted with a cleaning company that failed to adequately and non-negligently perform the work it was hired to do.

200. The Clinic Related Defendants failed to inform their patients, including Plaintiffs, that they were receiving a drug produced from a compounding pharmacy, much less a compounding pharmacy with the characteristics and problems as described in the preceding paragraphs.

201. The Clinic Related Defendants failed to inform their patients, including Plaintiffs, that they were receiving a drug that was not approved by the FDA. They also failed to inform the Plaintiffs that the drugs were obtained via mail order from a pharmacy in Massachusetts that was neither inspected by the FDA nor was accredited by any valid accrediting body. Such information is objectively material information to a reasonable patient's decision to undergo a procedure using such medication.

202. On the contrary, upon information and belief, many if not all of the Clinic Related Defendants failed to inform its patients, including Plaintiffs, that the drugs obtained from NECC and administered to Plaintiffs and/or injected into Plaintiffs' spinal canal were not, in fact, the name brand drug produced by a FDA-regulated laboratory and/or generic drugs produced by a FDA-regulated laboratory.

203. At all relevant times, Plaintiffs never received a drug produced to the same high quality standards name brand or generic drugs produced by FDA-regulated manufacturers from the Clinic Related Defendants and were never informed of the Clinic Related Defendants choice to purchase the drugs administered to them from an un-accredited facility like NECC.

204. In connection with the Clinic Related Defendants obtaining NECC's preservative free drugs for its patients, including Plaintiffs, the Clinic Related Defendants either failed to take

or negligently performed the reasonable and necessary due diligence and investigatory steps and measures necessary to vet, evaluate and determine the safety and quality of NECC's products, and in particular, determine if NECC could properly and suitably compound, package and provide sterile preservative free drugs for use by the Clinic Related Defendants in procedures on the Plaintiffs.

205. At all times and places pertinent to this action, the drugs that the Clinic Related Defendants voluntarily purchased from NECC and then sold and provided to their patients, including Plaintiffs, were contaminated with fungus, mold, and/or other contaminates, and therefore unsafe and unreasonably dangerous.

206. As a direct and proximate result of the Clinic Related Defendants wrongful conduct, the Plaintiffs were administered contaminated products by the Clinic Related Defendants, causing serious injuries to the Plaintiffs, and at times death.

VI. GENERAL ALLEGATIONS

207. As a direct and proximate result of NECC contaminated drugs and the Defendants' wrongful conduct, each Plaintiff, or their Estate, has suffered and will continue to suffer serious physical injuries, in addition to pain, suffering, mental anguish, fright, shock, denial of social pleasures and enjoyments, embarrassment, humiliation and mortification, emotional distress, and further has incurred and will continue to incur medical and other expenses as a direct result of being exposed to NECC's Contaminated Drugs. Further, many living Plaintiffs have suffered and will continue to suffer a loss of earning capacity.

208. Further, as a direct and proximate result of the NECC Contaminated Drugs, each survivor of each Decedent, suffered, and still suffers, the following damages, among others:

a. Medical, Hospital, Funeral and Burial expenses;

b. The loss the of financial support, loss of services, loss of gifts or other valuable gratuities, loss of parental training and guidance, loss of society and companionship, and all other damages permitted under their home State's Wrongful Death Act including all economic and non-economic losses.

209. Further, as a direct and proximate result of the NECC Contaminated Drugs, each spouse of each Plaintiff, lawfully married, suffered, and will continue to suffer, expenses related to the necessary medical care, treatment and services rendered to their spouse, the loss of services that they would have been provided had their spouse not been injured, and the loss of society and companionship and incidents of the marital relationship of which they have been deprived.

210. Further, as a direct and proximate result of the NECC Contaminated Drugs, each child and/or parent of each Plaintiff, suffered, and will continue to suffer, expenses related to the necessary medical care, treatment and services rendered to their loved one, the loss of services that their loved one would have provided them had their loved one not been injured and/or died, and the loss of society and companionship and incidents of the parent-child relationship of which they have been deprived.

VII. CAUSES OF ACTION[5]

COUNT I – NEGLIGENCE AND GROSS NEGLIGENCE (Against Liberty)

211. All allegations above are incorporated herein by reference.

212. Liberty owed Plaintiffs a duty to exercise reasonable care and to follow all applicable laws and standards during the manufacture, construction, installation, design, certification, and ongoing maintenance of the Cleanrooms in order to prevent or eliminate contamination of the Cleanrooms.

[5] The Court has addressed additional causes of actions not asserted in this Master Complaint in earlier decisions on clinic related defendants' motions to dismiss.

213. Liberty failed to exercise reasonable care in one or more of the following ways, so far as is presently known:

a. by failing to properly design and install the 2006 and 2008 Cleanroom ceiling grids, ceiling panels, light fixtures, and HEPA filtration modules;

b. by failing to properly design and install the 2006 and 2008 Cleanroom fire suppression system;

c. by failing to use proper materials in the construction of the ceiling of the Cleanrooms;

d. by failing to properly survey existing Cleanrooms and the facility as a whole to properly assess the risks associated with construction of subsequent Cleanrooms;

e. by failing to install a hard cap/hard ceiling over the ceiling of each Cleanroom to protect from contamination, despite Liberty's actual and/or constructive knowledge that the areas between the ceilings of the 2006 and 2008 Cleanrooms were prone to excessive contamination and water damage;

f. by prematurely certifying the 2006 and 2008 Cleanrooms;

g. by disrupting or otherwise breaching the cleanliness of the Cleanrooms through the installation of faulty ceiling grids, improper materials, and the conduct of subsequent work to each Cleanroom, resulting in or contributing to their contamination;

h. by failing to take reasonable steps to properly certify the Cleanrooms to ensure their cleanliness as required for their anticipated use;

i. by committing other violations as shall be revealed in discovery.

214. Each Plaintiff was a foreseeable victim of Liberty's negligence. Liberty knew that NECC and Ameridose were compounding drugs at their facility for national distribution and for use in patients such as Plaintiffs.

215. Liberty's wrongful conduct and negligence resulted in Plaintiffs' suffering serious physical injuries, distress and/or death.

216. As a direct and proximate result of Liberty's negligence, as well as that of Liberty's employees, agents, independent contractors, businesses, or others associated with and/or providing services, Plaintiffs' are entitled to recover all allowable elements of damages from Liberty in an amount that is just and appropriate to fully compensate Plaintiffs, decedent's estate, beneficiaries and/or next of kin for the serious physical injuries and/or wrongful deaths of Plaintiffs, plus interest and costs.

217. Liberty's conduct set out above constitutes gross negligence and a reckless disregard for human life and safety, thus warranting the imposition of punitive damages.

WHEREFORE, the Plaintiffs demand judgment against Liberty on Count I of this Complaint, in an amount that will justly compensate Plaintiffs for their damages, together with interest, costs and attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT II – NEGLIGENCE AND GROSS NEGLIGENCE
(Against UniFirst)

218. All allegations above are incorporated herein by reference.

219. UniFirst owed Plaintiffs a duty to exercise reasonable care to follow all applicable laws and standards, as well as NECC standard procedures, during the ongoing and regular maintenance and cleaning of the Cleanrooms in order to prevent or eliminate contamination of the Cleanrooms.

220. UniFirst knew or should have known that products produced, sold, and shipped by NECC required a sterile environment, and that such products would be used by end consumers such as Plaintiffs. UniFirst knew that end consumers of NECC products were the intended beneficiaries of the services to be rendered by UniFirst to NECC. UniFirst's knew that customers of a business like NECC expect and rely upon a clean and a safe environment for the production of goods. UniFirst knew this for nearly four years before the recall of the NECC Contaminated Drugs.

221. UniFirst failed to exercise reasonable care in one or more of the following ways, so far as is presently known:

a) UniFirst employees, contractors and/or representatives, including those within the UniClean division, entered the Cleanrooms (including the anterooms) in street clothes, without donning sterile or contaminant-free clothing such as shoe covers, hair caps, coveralls, and gloves that were readily available at the NECC facilities, thereby failing to follow its own standards and policies;

b) UniFirst employees, contractors and/or representatives brought into the NECC anterooms and Cleanrooms cleaning equipment, including mops, mop heads, spongers, and buckets that had been moved through exterior environments, even though such equipment had not been sanitized or cleaned appropriately, allowing contamination to occur throughout various parts of the NECC facility, such actions failing to meet UniFirst's own standards as well as recognized industry standards;

c) UniFirst employees, contractors and/or representatives failed to clean or wipe footwear on mats used in the cleanroom entry process, thereby allowing contaminants into and throughout the Cleanrooms; and

d) UniFirst employees, agents, contractors and/or representatives were negligently supervised, and failed to adhere to and follow NECC standard operating procedures.

222. Each Plaintiff was a foreseeable victim of UniFirst's negligence. UniFirst knew that the Affiliated Defendants were compounding drugs at their facility for national distribution and for use in patients such as Plaintiffs.

223. The wrongful conduct and negligence of UniFirst resulted in Plaintiffs' suffering serious physical injuries, distress and/or death.

224. As a direct and proximate result of UniFirst's negligence, as well as that of UniFirst's employees, agents, independent contractors, businesses, or others associated with and/or providing services, Plaintiffs' are entitled to recover all allowable elements of damage from UniFirst in an amount that is just and appropriate to fully compensate Plaintiffs, decedent's estate, beneficiaries and/or next of kin for the serious physical injuries and/or wrongful deaths of Plaintiffs, plus interest and costs.

225. UniFirst's conduct set out above constitutes gross negligence and a reckless disregard for human life and safety, thus warranting the imposition of punitive damages.

WHEREFORE, the Plaintiffs demand judgment against UniFirst on Count II of this Complaint, in an amount that will justly compensate Plaintiffs for their damages, together with interest, costs and attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT III - NEGLIGENCE AND GROSS NEGLIGENCE[6]
(Against Clinic Related Defendants)

226. All allegations above are incorporated herein by reference.

227. The Clinic Related Defendants had a duty to exercise reasonable care to ensure that the drugs they purchased in order to sell and administer to their patients, including Plaintiffs, were purchased from drug companies that complied with the laws regarding pharmaceuticals.

228. The Clinic Related Defendants had a duty to exercise reasonable care to ensure that the drugs they provided to their patients, including Plaintiffs, were purchased from a company that made safe and effective drugs.

229. The Clinic Related Defendants had a duty to exercise reasonable care to ensure that the drugs they provided to their patients, including Plaintiffs, were purchased from a company that utilized proper quality control, safety, and sterility measures in order to minimize the possibility that the drugs would become adulterated or contaminated.

230. The Clinic Related Defendants had a duty to exercise reasonable care to avoid administering contaminated drugs, or drugs they knew or should have known to be contaminated, to Plaintiffs.

231. The Clinic Related Defendants had a duty to provide Plaintiffs with reasonable care and treatment.

232. The Clinic Related Defendants had a duty to obtain informed consent from Plaintiffs for the procedure performed on Plaintiffs, adequately and accurately describing to

[6] The Court denied defendants' motions to dismiss the following claims for negligence and/or gross negligence in: (i) Tennessee against the Tennessee Clinic Defendants where claims will be evaluated under the Tennessee Health Care Liability Act, Tenn. Code Ann. 29-26-101(a)(1) [Dkt. 1360]; (ii) New Jersey against the Premier Defendants [Dkt. 1360]; (iii) Texas against Dallas Back Pain Management/Momentum Pain Management and Abbeselom Ghermay, M.D. [Dkt. 1556]; (iv) Illinois against Advanced Pain & Anesthesia Consultants, P.C. and Randolph Y. Chang, M.D. [Dkt. 1642]; and (v) Ohio against BKC Pain Specialists, Adil Kataby, M.D., and Nikesh Batra, M.D. [Dkt. 1643].

Plaintiffs the nature of the procedure, as well as the risks of such procedure, including the drugs that were to be administered during such procedure.

233. In this case, where the drug came from an unaccredited, mass producing, out-of-state, compounding pharmacy, unregulated by the FDA, the Clinic Related Defendants had a duty to inform Plaintiffs of the source of the drug and the dangers associated therewith.

234. The Clinic Related Defendants breached their duties to Plaintiffs in many respects, including, without limitation:

a. The Clinic Related Defendants failed to exercise reasonable and prudent care to ensure that the drug they purchased and provided to Plaintiffs were made by NECC in compliance with all applicable pharmaceutical laws;

b. The Clinic Related Defendants failed to exercise reasonable and prudent care to ensure that the drug they purchased and provided to Plaintiffs were sold to them by NECC in compliance with all applicable pharmaceutical laws;

c. The Clinic Related Defendants failed to know and understand the source and supply of the drug they provided to Plaintiffs;

d. The Clinic Related Defendants failed to use the appropriate, necessary and reasonable due diligence and investigatory steps and measures necessary to vet, evaluate and determine the safety and quality of NECC's drugs, and in particular, determine if NECC could properly and suitably compound, package and provide sterile preservative free drugs for administration to Plaintiffs;

e. The Clinic Related Defendants failed to follow the reasonable ASHP *Guidelines on Outsourcing Sterile Compounding Services*, which had they followed, would have established that NECC's products were unsuitable for administration to the Plaintiffs;

f. The Clinic Related Defendants failed to exercise reasonable and prudent care to ensure that the drug they provided to Plaintiffs were produced in sanitary, sterile conditions;

g. The Clinic Related Defendants failed to properly inform Plaintiffs that the use of the drug was not approved by the FDA;

h. The Clinic Related Defendants failed to properly inform Plaintiffs of the risks and dangers associated with the administration of the drug; and they failed to

inform them that they had obtained the drug from NECC, a mass-producing, unaccredited, non-FDA regulated compounding pharmacy;

i. The Clinic Related Defendants failed to exercise reasonable care to avoid administering to Plaintiffs an adulterated, contaminated and unreasonably dangerous drug;

j. The Clinic Related Defendants failed to conduct adequate due diligence regarding whether NECC was a reputable and safe supplier of sterile injectable compounds;

k. The Clinic Related Defendants failed to visit NECC's facilities before procuring compounded drugs, and other medicines, from NECC;

l. The Clinic Related Defendants failed to investigate and exercise sufficient due diligence before administering drugs procured from NECC, including failing to investigate or inquire concerning NECC's compounding practices, standard operating procedures, pharmacist training, and risk management protocols;

m. The Clinic Related Defendants failed to determine whether NECC had a history of recalling compounded medications before procuring medicines from that company;

n. The Clinic Related Defendants failed to investigate NECC's regulatory history with the FDA and/or the Massachusetts Board of Registration in Pharmacy before procuring drugs from NECC;

o. The Clinic Related Defendants failed to determine whether NECC had a history of product liability suits before procuring medicines from that company;

p. The Clinic Related Defendants failed to keep abreast of the dangers of sterile compounding;

q. The Clinic Related Defendants purchased compounded drugs in bulk from NECC without using patient specific individual prescriptions;

r. Many of the Clinic Related Defendants failed to appropriately store drugs purchased from NECC to reduce the risk of the growth of contaminants;

s. The Clinic Related Defendants failed to adequately supervise and train the physicians, nurses, agents and employees who ordered drugs from NECC;

t. The Clinic Related Defendants failed to implement policies and procedures that would prevent the procurement of purportedly sterile drugs from an out-of-state compounding pharmacy with a deplorable facility and sterility

procedures, a checkered regulatory past, product recall problems, and a history of product liability suits;

u. The Clinic Related Defendants administered drugs to Plaintiffs' without taking reasonable steps to ensure that those medicines were from a reputable supplier and were not contaminated with lethal pathogens;

v. The Clinic Related Defendants failed to promptly notify Plaintiffs that they were injected with potentially contaminated steroids and failed to recommend that they receive prompt treatment of their potential infections and other symptoms; and

w. The Clinic Related Defendants failed to exercise reasonable care in such other manners as may be shown through discovery and at trial.

235. The physicians, nurses, agents, employees and representatives who decided to procure drugs from NECC and who administered them to the Plaintiffs were employees or agents of the Clinic Related Defendants, and they were acting within the course and scope of their employment or agency. Accordingly, the Clinic Related Defendants are liable for the consequences of said person's or persons' conduct pursuant to the doctrine of *respondeat superior*.

236. The negligence of the Clinic Related Defendants proximately caused Plaintiffs' injuries, distress, and/or death.

237. The foregoing acts and omissions by the Clinic Related Defendants went beyond mere thoughtlessness, inadvertence or error of judgment.

238. The actions of the Clinic Related Defendants did not meet even the most minimal diligence to ensure that they were not injecting contaminated, adulterated, tainted, and unreasonably dangerous drugs directly into the bodies of their patients, including Plaintiffs.

239. The acts and omissions of the Clinic Related Defendants constituted such utter disregard for the rights of others, and such utter disregard for prudence, that they amount to complete neglect of the safety of patients, including Plaintiffs.

240. The acts and omissions of the Clinic Related Defendants were a heedless and palpable violation of their legal duties respecting the life and rights of Plaintiffs and constitute gross negligence.

241. Plaintiffs' injuries, distress, and/or death occurred as a proximate result of the grossly negligent acts and omissions of the Clinic Related Defendants.

242. Plaintiffs are entitled to recovery of damages, including punitive damages, for the unnecessary infection, emotional distress and personal injury caused by the negligence and/or grossly negligent acts and omissions of the Clinic Related Defendants.

WHEREFORE, Plaintiffs demand judgment against The Clinic Related Defendants, jointly and severally, on Count III of this Complaint, in an amount that will justly compensate for the damages, together with interest, costs and his attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT IV – VIOLATION OF STATE CONSUMER PROTECTION STATUTES
(Against Clinic Related Defendants)

(NOTE: The following count lists the consumer protection statutes of all 50 states and the District of Columbia. It is up to each Plaintiff to comply with the pre-suit notice and demand requirements of the state statutes asserted in their Short Form Complaint, if any)

243. All allegations above are incorporated herein by reference.

244. Clinic Related Defendants engaged in trade and commerce within the Commonwealth of Massachusetts and/or the states of the various Clinic Related Defendants.

245. Clinic Related Defendants' negligence, gross negligence, failure to warn, and civil conspiracy alleged herein constitute unfair competition or unfair or deceptive acts or practices or constitute false representations in violation of various state consumer protection statutes. Clinic Related Defendants' failure to perform and fulfill its promises, representations, and obligations to their patients, including Plaintiffs, constitutes an actionable violation.

246. As described herein, Clinic Related Defendants represented to their patients, including Plaintiffs, that the products administered had characteristics, uses and benefits that they did not have.

247. As describe herein, Clinic Related Defendants represented that their products were of a particular standard, quality and grade that they either knew or should have known was not of the standard, quality or grade described.

248. Clinic Related Defendants failed to provide accurate disclosures of all material information before Plaintiffs agreed to be injected with an NECC Contaminated Drug.

249. Clinic Related Defendants willfully and knowingly failed to abide by regulations, laws and guidelines set forth to protect consumer safety, constituting a violation of the consumer protection statutes set forth herein.

250. Clinic Related Defendants' willful and knowing withholding of important safety information and critical product information constitutes a violation of various state consumer protection statutes set forth herein.

251. Clinic Related Defendants actively, knowingly, and deceptively concealed the product's dangerous properties and life-threatening risks of which they knew or should have known. This conduct evidences bad faith and unfair and deceptive practices.

252. Clinic Related Defendants engaged in the conduct as described herein that created a likelihood of confusion and misunderstanding.

253. Many Clinic Related Defendants represented their patients, including Plaintiffs, were receiving FDA-approved Depomedrol when in fact they injected patients, including Plaintiffs with NECC's compounded MPA.

254. Clinic Related Defendants engaged in the conduct as described herein that created a likelihood of causing injury to unknowing consumers, including Plaintiffs.

255. Clinic Related Defendants' conduct as described herein constituted unfair and deceptive acts and practices, including, but not limited to:

a. Misrepresenting the nature, quality, and characteristics about the products they sold and administered to Plaintiffs;

b. Unfairly violating regulations, laws and guidelines set forth to protect consumer safety;

c. Unfairly exposing unknowing consumers, including Plaintiffs, to significant, unnecessary risk of harm and actual harm and injury; and

d. All other unfair and deceptive acts set forth herein.

256. The practices described herein are unfair because they offend public policy as established by statutes, the common law, or otherwise. Additionally Clinic Related Defendants were unethical and unscrupulous, and caused substantial injury to consumers. Clinic Related Defendants engaged in unconscionable actions and courses of action.

257. Clinic Related Defendants willfully engaged in the conduct described herein, which they knew was deceptive, in the course of business, trade and commerce, and had a deleterious impact on the public interest.

258. Clinic Related Defendants are liable to Plaintiffs for all statutory, direct and consequential damages, and fees and costs resulting from this breach, including multiple damages.

259. Plaintiffs were injected with NECC Contaminated Drugs for personal use and thereby suffered ascertainable losses as a result of the Clinic Related Defendants' actions in violation of the consumer protection laws.

260. Had Clinic Related Defendants not engaged in the deceptive conduct described herein, Plaintiffs would not have allowed for the administration of NECC Contaminated Drugs, and would not have incurred related medical costs and injury, and at times, death.

261. Clinic Related Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, money from Plaintiffs for the NECC Contaminated Drugs that would not have been paid had Clinic Related Defendants not engaged in unfair and deceptive conduct.

262. Clinic Related Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the promotion and sale of the NECC Contaminated Drugs.

263. Had Clinic Related Defendants not engaged in the deceptive conduct described above, Plaintiffs would not have purchased and/or paid for NECC Contaminated Drugs, and would not have incurred related medical costs.

264. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state consumer protection statutes, as listed below.

- Ala. Code §§ 8-19-1 et seq.;
- Alaska Stat. §§ 45.50.471 et seq.;
- Ariz. Rev. Stat. Ann. §§ 44-1522 et seq.;
- Ark. Code Ann. §§ 4-88-101 et seq.;
- Cal. Civ. Code §§ 1770 et seq. and Cal. Bus. & Prof. Code §§ 17200 et seq.;

- Colo. Rev. Stat. §§ 6-1-105 et seq.;
- Conn. Gen. Stat. §§ 42-110a et seq.;
- Del. Code Ann. tit. 6, §§ 2511 et seq. and §§ 2531 et seq.;
- D.C. Code Ann. §§ 28-3901 et seq.;
- Fla. Stat. Ann. §§ 501.201 et seq.;
- O.C.G.A. §§ 10-1-372 et seq.;
- Haw. Rev. Stat. §§ 480-1 et seq.;
- Id. Code Ann. §§ 48-601 et seq.;
- Ill. Comp. Stat. Ann ch. 815, 505/1 et seq.;[7]
- Ind. Code Ann. §§ 24-5-0.5-1 et seq.;
- Iowa Code Ann. §§ 714.16 et seq.;
- Kan. Stat. Ann. §§ 50-623 et seq.;
- Ky. Rev. Stat. Ann. §§ 367.170 et seq.;
- La. Rev. Stat. Ann. §§ 51:1401 et seq.;
- Me. Rev. Stat. Ann. tit. 5, §§ 205A et seq.;
- Md. Code Ann., Com. Law §§ 13-101 et seq.;
- Mass. Gen. Laws Ann. Ch. 93A et seq.;
- Mich. Comp. Laws §§ 445.901 et seq.;
- Minn. Stat. §§ 325D.43 et seq. and §§ 325F.67 et seq.;
- Miss. Code Ann. §§ 75-24-1 et seq.;
- Mo. Ann. Stat. §§ 407.010 et seq.;

[7] The Court denied defendants' motion to dismiss claims under the Illinois Consumer Fraud Act against Advanced Pain & Anesthesia Consultants, P.C. and Randolph Y. Chang, M.D. [Dkt. 1642].

- Mont. Code Ann. §§ 30-14-101 et seq.;
- Neb. Rev. Stat. §§ 59-1601 et seq.;
- Nev. Rev. Stat. §§ 598.0903 et seq.;
- N.H. Rev. Stat. Ann. §§ 358-A:1 et seq.;
- N.M. Stat. Ann. §§ 57-12-1 et seq.;
- N.Y. Gen. Bus. Law §§ 349 et seq. and §§ 350-e et seq.;
- N.C. Gen. Stat. §§ 75-1.1 et seq.;
- N.D. Cent. Code §§ 51-12-01 et seq. and §§ 51-15-01 et seq.;
- Ohio Rev. Code Ann. §§ 1345.01 et seq.;[8]
- Okla. Stat. tit. 15 §§ 751 et seq.;
- Or. Rev. Stat. §§ 646.605 et seq.;
- 73 Pa. Stat. §§ 201-1 et seq.;
- R.I. Gen. Laws. §§ 6-13.1-1 et seq.;
- S.C. Code Ann. §§ 39-5-10 et seq.;
- S.D. Codified Laws §§ 37-24-1 et seq.;
- Tenn. Code Ann. §§ 47-18-101 et seq.;[9]
- Tex. Bus. & Com. Code Ann. §§17.41 et seq.;[10]
- Utah Code Ann. §§ 13-11-1 et seq.;
- Vt. Stat. Ann. tit. 9, §§ 2451 et seq.;

[8] The Court denied defendants' motion to dismiss claims under the Ohio Consumer Sales Practices Act against BKC Pain Specialists but dismissed such claims as to Adil Kataby, M.D. and Nikesh Batra, M.D. [Dkt. 1643].
[9] The Court denied defendants' motion to dismiss claims under Tennessee Consumer Protection Act against the Tennessee Clinic Defendants as to recovery for money used to purchase MPA but dismissed such claims as to recovery for personal injury or wrongful death [Dkt. 1360].
[10] The Court denied defendants' motion to dismiss claims under the Texas Deceptive Trade Practices Act against Dallas Back Pain Management/Momentum Pain Management and Abbeselom Ghermay, M.D. [Dkt. 1556].

- Va. Code Ann. §§ 59.1-196 et seq.;
- Wash. Rev. Code. §§ 19.86.010 et seq.;
- W. Va. Code §§ 46A-6-101 et seq.;
- Wis. Stat. Ann. §§ 100.20 et seq.; and
- Wyo. Stat. Ann. §§ 40-12-101 et seq.

265. Under the statutes listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Clinic Related Defendants are the suppliers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

266. Clinic Related Defendants violated the statutes that were enacted in these states to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the NECC Contaminated Drugs were fit to be used for the purpose for which they were intended, when, in fact, they were defective and dangerous, and by other acts alleged herein.

267. The actions and omissions of Clinic Related Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

268. Plaintiffs relied upon Clinic Related Defendants' misrepresentations and omissions in determining which product to use.

269. Clinic Related Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

270. By reason of the unlawful acts engaged in by Clinic Related Defendants, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

271. As a direct and proximate result of Clinic Related Defendants' violations of the states' consumer protection laws, Plaintiffs have sustained economic losses and other damages and are entitled to statutory and compensatory, damages in an amount to be proven at trial.

WHEREFORE, the Plaintiffs demand judgment against Clinic Related Defendants, on Count IV of this Complaint, in an amount that will justly compensate for the damages, together with interest, costs and his attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT V – VIOLATION OF M.G.L. c.93A
(Against Liberty)

(NOTE: It is up to each Plaintiff to comply with the pre-suit notice and demand requirements of M.G.L. c. 93A as alleged in their Short Form Complaint)

272. All allegations above are incorporated herein by reference.

273. Liberty engaged in trade and commerce within the Commonwealth of Massachusetts within the meaning of M.G.L. c. 93A.

274. Liberty's negligence and gross negligence alleged herein constitutes unfair competition or unfair or deceptive acts or practices or constitute false representations in violation of M.G.L. c. 93A.

275. Liberty willfully and knowingly failed to abide by regulations, laws and guidelines set forth to protect consumer safety in the design and construction of the Cleanrooms, constituting a violation of the Act.

276. Liberty engaged in the conduct as described herein that created a likelihood of causing injury to unknowing consumers, including Plaintiffs.

277. The practices described herein are unfair because they offend public policy as established by statutes, the common law, or otherwise. Liberty engaged in unconscionable actions and courses of action.

278. Liberty willfully engaged in the conduct described herein, which they knew or should have known was deceptive, in the course of business, trade and commerce, and had a deleterious impact on the public interest.

279. Liberty is liable to Plaintiffs for all statutory, direct and consequential damages, and fees and costs resulting from this breach, including multiple damages.

280. Plaintiffs were injected with NECC Contaminated Drugs for personal use and thereby suffered ascertainable losses as a result of Liberty's actions in violation of the consumer protection laws.

281. Had Liberty not engaged in the deceptive conduct described herein, Plaintiffs would not have been injected with contaminated drugs, and would not have incurred related medical costs and injury, and at times, death.

282. Liberty's actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of M.G.L. c. 93A.

283. By reason of the unlawful acts engaged in by Liberty, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

WHEREFORE, the Plaintiffs demand judgment against Liberty on Count V of this Complaint, in an amount that will justly compensate for the damages, together with interest, costs and his attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT VI – VIOLATION OF M.G.L. c.93A
(Against UniFirst)

(NOTE: It is up to each Plaintiff to comply with the pre-suit notice and demand requirements of M.G.L. c. 93A as alleged in their Short Form Complaint)

284. All allegations above are incorporated herein by reference.

285. UniFirst engaged in trade and commerce within the Commonwealth of Massachusetts within the meaning of M.G.L. c. 93A.

286. UniFirst's negligence and gross negligence alleged herein constitutes unfair competition or unfair or deceptive acts or practices or constitute false representations in violation of M.G.L. c. 93A.

287. UniFirst willfully and knowingly failed to abide by regulations, laws and guidelines, including NECC standard operating procedures, set forth to protect consumer safety in the cleaning and ongoing maintenance of NECC and Ameridose facilities, including the Cleanrooms, constituting a violation of the Act.

288. UniFirst engaged in the conduct as described herein that created a likelihood of causing injury to unknowing consumers, including Plaintiffs.

289. The practices described herein are unfair because they offend public policy as established by statutes, the common law, or otherwise. UniFirst engaged in unconscionable actions and courses of action.

290. UniFirst willfully engaged in the conduct described herein, which they knew or should have known was deceptive, in the course of business, trade and commerce, and had a deleterious impact on the public interest.

291. UniFirst is liable to Plaintiffs for all statutory, direct and consequential damages, and fees and costs resulting from this breach, including multiple damages.

292. Plaintiffs were injected with NECC Contaminated Drugs for personal use and thereby suffered ascertainable losses as a result of UniFirst's actions in violation of the consumer protection laws.

293. Had UniFirst not engaged in the deceptive conduct described herein, Plaintiffs would not have been injected with contaminated drugs, and would not have incurred related medical costs and injury, and at times, death.

294. UniFirst's actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of M.G.L. c. 93A.

295. By reason of the unlawful acts engaged in by UniFirst, and as a direct and proximate result thereof, Plaintiffs have suffered ascertainable losses and damages.

WHEREFORE, the Plaintiffs demand judgment against UniFirst, on Count VI of this Complaint, in an amount that will justly compensate for the damages, together with interest, costs and his attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT VII - BATTERY
(Against Clinic Related Defendants)

In recognition of earlier rulings of the MDL Court on various dispositive motions, the allegations of battery contained in paragraphs 296 through 298 of the original Master Complaint (Doc. 545) have been eliminated.[11]

COUNT VIII - FAILURE TO WARN[12]

[11] The Court granted defendants' motions to dismiss claims for battery in: (i) Tennessee against the Tennessee Clinic Defendants [Dkt. 1360]; and (ii) New Jersey against the Premier Defendants [Dkt. 1360].
[12] The Court denied defendants' motions to dismiss claims for failure to warn in: (i) Tennessee against the Tennessee Clinic Defendants that ordered and administered injections but dismissed such claims as to those that neither ordered nor administered injections and such survived claims will be evaluated under the Tennessee Health Care Liability Act, Tenn. Code Ann. 29-26-101(a)(1) [Dkt. 1360]; (ii) New Jersey against the Premier Defendants [Dkt. 1360]; (iii) Texas against Dallas Back Pain Management/Momentum Pain Management and Abbeselom Ghermay, M.D. where such claims will be treated as informed consent under Tex. Civ. Prac. & Rem. Code 74.01

(Against Clinic Related Defendants)

296. All allegations above are incorporated herein by reference.

297. The Clinic Related Defendants provided high risk and unreasonably dangerous NECC Contaminated Drugs to patients, including Plaintiffs, in the place of safe, medically acceptable drugs.

298. The Clinic Related Defendants failed to inform their patients, including Plaintiffs, that they were being administered an unsafe, unreasonably dangerous drug compounded by NECC rather than a high quality drug produced by an FDA regulated manufacturer.

299. Many, if not all, of the Clinic Related Defendants prepared a Consent for Treatment Form. The form, which was presented to Plaintiffs by the Clinic Related Defendants, and which Plaintiffs read and relied upon when agreeing to accept treatment, failed to inform the Plaintiffs of the risks and benefits of the procedures before it was performed. When presenting the form to Plaintiffs, the Clinic Related Defendants knew that nobody on its behalf would be informing Plaintiffs of the inferior and unreasonably dangerous nature of the NECC drug that would be administered to Plaintiffs. Clinic Related Defendants knew that if Plaintiffs were informed of the true nature of the NECC drugs, Plaintiffs would decline treatment with NECC drugs, threatening the Healthcare Providers' profits.

300. As a proximate result of the Clinic Related Defendants' wrongful conduct, Plaintiffs suffered grievous bodily injury and/or death, have required extensive medical treatment, have incurred and in the future will incur substantial medical bills and have suffered and will in the future suffer inconvenience and severe mental anguish.

[Dkt. 1556]; and (iv) Illinois against Advanced Pain & Anesthesia Consultants, P.C. and Randolph Y. Chang, M.D. [Dkt. 1642]. The Court granted defendants' motion to dismiss claims for failure to warn in Ohio against BKC Pain Specialists, Adil Kataby, M.D., and Nikesh Batra, M.D. [Dkt. 1643].

WHEREFORE, Plaintiffs demand judgment against Defendants on Count VIII of this Complaint, in an amount that will justly compensate for the damages, together with interest, costs and his attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT IX - TENNESSEE PRODUCT LIABILITY CLAIMS[13]
(Against Tennessee Clinic Related Defendants)

301. All allegations above are incorporated herein by reference.

302. The drugs administered to the Plaintiffs were compounded by NECC.

303. On December 21, 2012, NECC filed a voluntary petition pursuant to Chapter 11 of Title 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Massachusetts, In re: New England Compounding Pharmacy, Inc., case no. 12-19882-HJB.

304. Pursuant to 11 U.S.C. § 362(a)(1) certain actions against NECC are stayed following its bankruptcy petition.

305. Plaintiffs could have commenced an action in this court seeking to recover on a claim and seeking a judgment against NECC before December 21, 2012.

306. Plaintiffs' claims that arose before NECC's petition in bankruptcy are subject to the automatic stay provisions of 11 U.S.C. § 362(a)(1).

307. NECC has ceased operations.

308. NECC is unable to pay its debts as they fall due.

309. NECC is unable to pay its debts in the ordinary course of its business.

310. NECC's liabilities exceed its assets.

311. NECC is insolvent.

[13] The Court denied defendants' motion to dismiss claims under the Tennessee Products Liability Act against the Tennessee Clinic Defendants and distinguished such claims from the Tennessee Health Care Liability Act, Tenn. Code Ann. 29-28-102, by the Court [Dkt. 1360].

312. On July 24, 2013, The United States Bankruptcy Court for the District of Massachusetts in In re: New England Compounding Pharmacy, Inc., Case no. 12-19882-HJB, ordered that with respect to certain claims, including those asserted by Plaintiffs in this lawsuit, NECC is presently insolvent and has been insolvent at all times since the petition date.

313. The Tennessee hospitals, clinics, healthcare facilities, their employees, agents, physicians and/or sub-contractors (collectively referred to as "Tennessee Healthcare Providers Defendants") procured the drugs administered to the Plaintiffs from NECC.

314. NECC's drugs were defective and unreasonably dangerous when it left NECC's control because it was contaminated with lethal pathogens.

315. NECC's drugs were in substantially the same condition at the time that the Tennessee Healthcare Providers Defendants administered it to the Plaintiffs.

316. The Tennessee Healthcare Providers Defendants charged Plaintiffs for the products administered to them.

317. The Tennessee Healthcare Providers Defendants acted as a seller or distributor of drugs compounded by NECC when it sold and administered the drugs to patients, including Plaintiffs.

318. The Tennessee Healthcare Providers Defendants were engaged in the business of selling drugs compounded by NECC.

319. Accordingly, the Tennessee Healthcare Providers Defendants are "sellers" as defined by Tenn. Code Ann. § 29-28-102(7).

320. Tenn. Code Ann. § 29-28-106(4) authorizes Plaintiffs to prosecute product liability claims against the Tennessee Healthcare Providers Defendants as the seller of the drugs

administered to the Plaintiffs because the compounder of the product, NECC, cannot be served with process in this state.

321. Tenn. Code Ann. § 29-28-106(5) authorizes Plaintiffs to prosecute product liability claims against the Tennessee Healthcare Providers Defendants as the seller of the drugs administered to the Plaintiffs because the compounder of the product, NECC, has been judicially declared insolvent.

322. The drugs that the Tennessee Healthcare Providers Defendants administered to the Plaintiffs were unreasonably dangerous and defective at the time it left their control because it was contaminated with lethal pathogens.

323. Specifically, NECC's drugs were in a defective condition and unreasonably dangerous at all relevant times because it was unsafe for normal or anticipated handling as defined by Tenn. Code Ann. § 29-28-102(2).

324. The NECC drugs sold and distributed by the Tennessee Healthcare Providers Defendants were neither merchantable nor fit for the purpose for which it was produced and sold. Accordingly, the Tennessee Healthcare Providers Defendants breached their warranties, both express and implied, as stated in Tenn. Code Ann. §§ 47-2-313, 47-2-314, and 47-2-315, including their warranty of fitness for a particular purpose.

325. The Tennessee Healthcare Providers Defendants are strictly liable for the injuries and losses caused by the unreasonably dangerous and defective NECC drugs administered to the Plaintiffs.

WHEREFORE, Plaintiffs demand judgment against Defendants, jointly and severally, on Count IX of this Complaint, in an amount that will justly compensate for the damages,

together with interest, costs and his attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT X - AGENCY[14]
(Against the Clinic Related Defendants)

In recognition of earlier rulings of the MDL Court on various dispositive motions, the allegations of agency contained in paragraphs 329 through 336 of the original Master Complaint (Doc. 545)(those allegations of agency in which a written agency agreement is not the basis of the claim) have been eliminated.

326. All allegations above are incorporated herein by reference.

327. At all times relevant herein, NECC was acting as an agent of the Clinic Related Defendants in compounding drugs to be administered to the Plaintiffs by the Clinic Related Defendants, pursuant to a written agency agreement between the Clinic Related Defendants and NECC

328. A consensual fiduciary relationship arose when the Clinic Related Defendants entered into a written agency agreement with NECC for the purpose of procuring compounded drugs from NECC for their patients, including Plaintiffs.

329. In the written agency agreement, the Clinic Related Defendants manifested assent for NECC to act as their agent, and on their behalf, when the Clinic Related Defendants contracted with NECC to procure compounded drugs from NECC to administer to their patients, including Plaintiffs.

[14] The Court granted defendants' motions to dismiss claims for agency in: (i) New Jersey against the Premier Defendants [Dkt. 1360]; and (ii) Texas against Dallas Back Pain Management/Momentum Pain Management and Abbeselom Ghermay, M.D. [Dkt. 1556]. Allegations of agency remaining in this Second Amended Master Complaint are intended to apply only to those cases in which the plaintiff has alleged the existence of a written agency agreement between the provider defendant and NECC.

330. In the written agency agreement, NECC consented to act as the Clinic Related Defendants' agent, and in the Clinic Related Defendants' interest, when compounding, selling and delivering its compounded drugs to the Clinic Related Defendants, to be sold and administered to the Clinic Related Defendants' patients, including the Plaintiffs.

331. At all times relevant herein, NECC acted within the scope of its agency with the Clinic Related Defendants. As set forth herein, NECC acted negligently and or exhibited gross negligence in the compounding of NECC contaminated drugs.

332. The Clinic Related Defendants controlled the procurement of the drugs from NECC to be sold and administered to their patients, including the Plaintiffs.

333. As a result, the Clinic Related Defendants are responsible for the negligence, gross negligence and wrongful conduct of NECC in compounding the contaminated drugs administered to Plaintiffs.

WHEREFORE, Plaintiffs demand judgment against the Clinic Related Defendants on Count X of this Complaint, in an amount that will justly compensate for the damages, together with interest, costs and their attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT XI – CIVIL CONSPIRACY[15]
(Against Clinic Related Defendants)

In recognition of earlier rulings of the MDL Court on various dispositive motions, the allegations of civil conspiracy contained in paragraphs 337 through 351 of the original Master Complaint (Doc. 545) have been eliminated.

[15] The Court granted defendants' motions to dismiss claims for civil conspiracy in: (i) Tennessee against the Tennessee Clinic Defendants [Dkt. 1360]; (ii) New Jersey against the Premier Defendants [Dkt. 1360]; and (iii) Texas against Dallas Back Pain Management/Momentum Pain Management and Abbeselom Ghermay, M.D. [Dkt. 1556].

COUNT XI-A – CIVIL CONSPIRACY[16]
(Against Saint Thomas Outpatient Neurosurgical Center, Howell Allen Clinic, Debra Schamberg, R.N. and John Culclasure, M.D.)[17]

In recognition of earlier rulings of the MDL Court on various dispositive motions, the allegations of civil conspiracy contained in paragraphs 364 through 387 of the First Amendment to Master Complaint [Dkt. 832] have been eliminated.

COUNT XII - WRONGFUL DEATH
(Against Each Defendant)

334. All allegations above are incorporated herein by reference.

335. Plaintiffs, individually and for the benefit of all wrongful death beneficiaries, sue pursuant to the wrongful death statute in effect in the states governing each of the Plaintiffs' claims, including:

- Ala. Code §§ 6-5-410 et seq.;
- Alaska Stat. §§ 09.55.580 et seq.;
- Ariz. Rev. Stat. Ann. §§ 12-611 et seq.;
- Ark. Code Ann. §§ 16-62-102(a)(1) et seq.;
- Cal. Civ. Code §§ 377.60 et seq.;
- Colo. Rev. Stat. §§ 13-21-201 et seq.;
- Conn. Gen. Stat. §§ 52-555 et seq.;
- Del. Code Ann. tit. 10 §§ 3724 et seq. and §§ 3721-3723 et seq.;
- D.C. Code Ann. §§ 16-2701 et seq.;
- Fla. Stat. Ann. §§ 768.16-26 et seq.;
- Ga. Code Ann.. §§ 51-4-1 to 51-4-5 et seq.;

[16] The Court granted defendants' motion to dismiss claims for civil conspiracy against all Tennessee Clinic Defendants including those named in this amended count [Dkt. 1360].
[17] This count specific to Tennessee defendants was incorporated by the PSC's First Amendment to Master Complaint [Dkt. 832].

- Haw. Rev. Stat. §§ 663-3 et seq.;
- Id. Code Ann. §§ 5-311 et seq.;
- 740 Ill. Comp. Stat. 180/0.01 et seq.;
- Ind. Code §§ 34-23-1-1 et seq.;
- Iowa Code §§ 633.336et seq.;
- Kan. Stat. Ann. §§ 60-1901 to 60-1905 et seq.;
- Ky. Rev. Stat. Ann. § 411.130 et seq.;
- La. Civ. Code. Ann. § 2315 et seq.;
- Me. Rev. Stat. Ann. tit. 18A, §2-804 et seq.;
- Md. Code Ann., Cts & Jud. Proc. §3-904 et seq.;
- Mass. Gen. Laws Ann. Ch. 229 §1 et seq.;
- Mich. Comp. Laws §§ 600.2922 et seq.;
- Minn. Stat. §§ 573.02 et seq.
- Miss. Code Ann. §§ 11-7-13 et seq.;
- Mo. Rev. Stat. §§ 537.080 et seq.;
- Mont. Code Ann. §§ 27-1-513 et seq.;
- Neb. Rev. Stat. §§ 30-809 et seq.;
- Nev. Rev. Stat. §§ 41.085 et seq.;
- N.H. Rev. Stat. Ann. §§ 556:12 et seq.;
- N.J. Stat. Ann. §§ 2A:31-1 et seq.
- N.M. Stat. Ann. §§ 41-2-1 et seq.;
- N.Y. Est. Powers & Trusts ("EPTL") §§ 5-4.1 et seq.;
- N.C. Gen. Stat. §§ 32-21-01 et seq.;

- N.D. Cent. Code §§ 51-12-01 et seq. and §§ 51-15-01 et seq.;
- Ohio Rev. Code Ann. §§ 2125.01 et seq.;
- Okla. Stat. tit. 12 §§ 1053 et seq.;
- Or. Rev. Stat. §§ 30.020 et seq.;
- 42 Pa. Cons. §§ 8302 et seq.;
- R.I. Gen. Laws. §§ 10-7-1 et seq.;
- S.C. Code Ann. §§ 15-51-10 et seq.;
- S.D. Codified Laws §§ 21-5-1 et seq.;
- Tenn. Code Ann. §§ 20-5-101 et seq.;
- Tex. Civ. Prac. & Rem. Code Ann. §§71.001 et seq.;
- Utah Code Ann. §§ 78B-3-106 et seq.;
- Vt. Stat. Ann. tit. 14, §§ 1491 et seq.;
- Va. Code Ann. §§ 8.01-50 et seq.;
- Wash. Rev. Code. §§ 4.20.010 et seq.;
- W. Va. Code §§ 55-7-5 et seq.;
- Wis. Stat. Ann. §§ 895.03 et seq.; and
- Wyo. Stat. Ann. §§ 1-38-101 et seq.

336. The conduct described herein was caused by Defendants' and their agents' employees' and servants' wrongful, negligent, and careless acts.

337. As a direct and proximate result of Defendants' conduct and omissions described herein, the NECC Contaminated Drugs administered to Plaintiffs caused the injuries and damages as described herein, including in some cases, death.

338. Plaintiffs seek damages for the fair monetary value of any Plaintiff decedents' injuries, physical conscious pain and suffering and mental and emotional anguish, the value of the Plaintiff decedents to each of the Plaintiffs and the beneficiaries of their estate, including but not limited to compensation for the loss of the reasonably expected net income, services, protection, care, assistance, society, companionship, comfort, guidance, counsel and advice of the Plaintiff decedents. Plaintiffs seek recovery for the reasonable medical and funeral expenses of the Plaintiff decedents.

339. Defendants' willful, wanton, and reckless acts and omission and gross negligence caused Plaintiff decedents' death and warrant the estate recovering punitive damages.

WHEREFORE, the Plaintiffs demand judgment against Defendants, jointly and severally, on Count XII of this Complaint, in an amount that will justly compensate for the damages, together with interest, costs and his attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT XIII – LOSS OF CONSORTIUM
(Against all Defendants)

340. All allegations above are incorporated herein by reference.

341. At all times material herein mentioned Plaintiff were husband and wife or were parent and child.

342. As a further direct and proximate result of the Defendants' negligence, gross negligence and other culpable acts, omissions and activities set out above, Plaintiffs have suffered the loss of his or her spouse, parent or child's services, companionship, society, and consortium, emotional distress and mental anguish, and will continue to suffer such loss and damages in the foreseeable future.

343. Plaintiff also has incurred and will incur expenses related to obtaining medical treatment and care for his or her spouse's, parent's or child's injuries.

WHEREFORE, the Plaintiffs demand judgment against Defendants, jointly and severally, on Count XIII of this Complaint, in an amount that will justly compensate for the damages, together with interest, costs and attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT XIV – PUNITIVE DAMAGES[18]
(Against all Defendants)

344. All allegations above are incorporated herein by reference.

345. The above described acts and omissions on the part of the Defendants were reckless and intentional. Defendants were aware of, but consciously disregarded, a substantial and unjustifiable risk of such a nature that their disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances. Plaintiffs therefore are entitled to an award of punitive damages against the Defendants.

WHEREFORE, the Plaintiffs demand judgment against Defendants, jointly and severally, on Count XIV of this Complaint, in an amount that will justly compensate for the damages, together with interest, costs and attorney fees incurred in this action, all within the jurisdictional limits of this Court.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs prays for relief against all Defendants, as follows:

[18] The Court denied defendants' motions to dismiss claims for punitive damage remedy in: (i) New Jersey against the Premier Defendants [Dkt. 1360]; (ii) Texas against Dallas Back Pain Management/Momentum Pain Management and Abbeselom Ghermay, M.D. [Dkt. 1556]; and (iii) Ohio against BKC Pain Specialists, Adil Kataby, M.D., and Nikesh Batra, M.D. [Dkt. 1643].

a. Compensatory damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiffs for all their injuries and damages, both past and present;

b. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiffs for all of their injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, and pain and suffering.

c. Exemplary damages

d. Punitive damages as allowed by law;

e. Attorneys' fees, expenses, and costs of this action;

f. Pre and post-judgment interest in the maximum amount allowed by law; and

g. Such further relief as this Court deems necessary, just, and proper.

IX. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury.

Dated: March 6, 2015

Respectfully submitted,

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Plaintiffs' Steering Committee

CERTIFICATE OF SERVICE

I, Patrick T. Fennell, hereby certify that I caused a copy of the above *Second Amended Master Complaint* to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access this filing through the Court's system, and notice of this filing will be sent to those parties by operation of the Court's CM/ECF system.

Dated: March 6, 2015

/s/Patrick T. Fennell
Patrick T. Fennell, VSB 40393